MVP Health Care Medical Policy

Medicare Part B: Ustekinumab

Type of Policy: Drug/Medical Therapy
Prior Approval Date: 10/01/2024
Approval Date: 10/01/2025
Effective Date: 01/01/2026

Related Policies: Abatacept, Certolizumab, Golimumab, Infliximab, Risankizumab, Tocilizumab

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Drugs Requiring Prior Authorization under the medical benefit
J3358 Stelara (ustekinumab intravenous injection, 1mg)
Q9994 Pyzchiva, ustekinumab-ttwe, intravenous, 1 mg
J3590 Yesintek, ustekinumab-kfce 130mg/26ml, intravenous, biosimilar, 1 mg

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Overview/Summary of Evidence

Ustekinumab (Stelara®) is a human IgG1 monoclonal antibody that binds to the p40 protein used by both IL-12 and IL-23 cytokines.

Ustekinumab is indicated for moderate to severe plaque psoriasis in members 6 years or older who are candidates for phototherapy or systemic therapy, active psoriatic arthritis (PsA) alone or in combination with methotrexate (MTX), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis (UC).

Members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.

- Self-administered formulations fall under the Medicare Part D (pharmacy) benefit.
    - Refer to the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.
- Must be ordered by or with consult from a rheumatologist, immunologist, dermatologist, gastroenterologist or colorectal surgeon
- Must be prescribed for an FDA approved indication

B. Psoriasis

Ustekinumab may be considered for coverage when the following criteria is met:

- Documentation of moderate to severe chronic plaque psoriasis OR involvement of the palms, soles of feet and scalp, with an inadequate response, intolerance or contraindication with TWO of the following therapies: Enbrel, Humira, Otezla, Skyrizi.

Initial approval will be for **6 months**

Extensions requests will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. Psoriatic Arthritis (PsA)

Ustekinumab may be considered for coverage when the following criteria is met:

- Documentation of active psoriatic arthritis with an inadequate response, intolerance or contraindication with TWO of the following therapies: Enbrel, Humira, Otezla, Xeljanz/XR.

Initial approval will be for **6 months**.

Extensions requests will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. Crohn's Disease

Ustekinumab may be considered for coverage when the following criteria is met:

- Documentation of moderate to severely active disease, with a previous trial, intolerance, or contraindication to Humira

Initial approval will be for **6 months**.

Extensions requests will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. Ulcerative Colitis

Ustekinumab may be considered for coverage when the following criteria is met:

- Documentation of moderately to severely active ulcerative colitis, with an inadequate response, intolerance, or contraindication to Humira and Xeljanz/XR.

Initial approval will be for **6 months.**

Extensions requests will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the ustekinumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

Exclusions

The use of ustekinumab will not be covered for the following situations:

- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- Combination therapy that is not supported by current guidelines

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References

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11. Pyzchiva [package insert]. Princeton, NJ: Sandoz; December 2024. Available from: Pyzchiva Package Insert

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