



MVP Health Care Medical Policy

Medicare Part B: Ustekinumab

Type of Policy: Drug/Medical Therapy

Prior Approval Date: 11/01/2023

Approval Date: 10/01/2024

Effective Date: 12/01/2024

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, J3357 Stelara (ustekinumab intravenous injection, 1mg)

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

References

1. Stelara injection, subcutaneous. Prescribing Information. Horsham, PA, Janssen Biotech Inc.; November 2019.
2. Ritchlin CT, Kavanaugh A, Gladman DD, et al: (2008) Treatment recommendations for psoriatic arthritis. *Ann Rheum Dis* 2009 Sep;68(9):1387-94.
3. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondylosrthritis Research

and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis and Rheumatology*. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: <https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf>

4. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis & Rheumatology* Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. [2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis](#)
5. ACG Clinical Guideline: Ulcerative Colitis in Adults. *The American Journal of Gastroenterology*: [March 2019 - Volume 114 - Issue 3 - p 384-413](#) doi: 10.14309/ajg.000000000000152. Accessed: [ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG \(lww.com\)](#)
6. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020;158:1450–1461; Published:January 13,2020 DOI:<https://doi.org/10.1053/j.gastro.2020.01.006>.
7. Feuerstein JD, Ho EY, Shmidt E, Singh H, Falck-Ytter Y, Sultan S, Terdiman JP; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021 Jun;160(7):2496–2508. doi: 10.1053/j.gastro.2021.04.022. PMID: 34051983; PMCID: PMC8988893.
8. Lichtenstein, Gary R MD, FACG¹; Loftus, Edward V MD, FACG²; Isaacs, Kim L MD, PhD, FACG³; Regueiro, Miguel D MD, FACG⁴; Gerson, Lauren B MD, MSc, MACG (GRADE Methodologist)^{5†}; Sands, Bruce E MD, MS, FACG⁶. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *American Journal of Gastroenterology*: April 2018 - Volume 113 - Issue 4 - p 481-517 doi: 10.1038/ajg.2018.27