

Ustekinumab Products
Effective 10/15/2025

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	Program Type	☒ Prior Authorization
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		☐ Quantity Limit ☐ Step Therapy
Specialty Limitations	These medications have been designated specialty and must be filled through a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Wezlana Iv is only available through the medical benefit		

Overview

Ustekinumab is a human interleukin-12 and -23 antagonist indicated for the treatment of adults with:

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Ustekinumab is also approved in pediatric patients 6 years of age and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis

Stelara, Wezlana and Yesintek are the preferred Ustekinumab products. All other Ustekinumab products are nonpreferred.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all the following diagnosis-specific criteria are met:

Moderate to severe plaque psoriasis

1. Diagnosis of moderate to severe plaque psoriasis
2. Member has at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
3. Member meets ONE of the following criteria:
 - a. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies
 - i. Corticosteroids (e.g., betamethasone, clobetasol)

- ii. Vitamin D analogs (e.g., calcitriol, calcipotriene)
 - iii. Tazarotene
 - iv. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
 - v. Anthralin
 - vi. Coal tar
 - b. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.
- 4. **Nonpreferred Ustekinumab formulations:** Trial and failure, intolerance, or contraindication to ONE of the following:
 - a. Stelara
 - b. Wezlana
 - c. Yesintek

Active psoriatic arthritis (PsA)

- 1. Diagnosis of active psoriatic arthritis
- 2. The member meets ONE of the following:
 - a. Actively inflamed joints
 - b. Dactylitis
 - c. Enthesitis
 - d. Axial disease
 - e. Active skin and/or nail involvement
- 2. **Nonpreferred Ustekinumab formulations:** Trial and failure, intolerance, or contraindication to ONE of the following:
 - a. Stelara
 - b. Wezlana
 - c. Yesintek

Moderately to severely active Crohn's disease (CD)

- 1. Diagnosis of moderately to severely active Crohn's disease
- 2. ONE of the following:
 - a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
 - i. 6-mercaptopurine
 - ii. Azathioprine
 - iii. Corticosteroids (e.g., prednisone)
 - iv. Methotrexate
 - b. Disease severity warrants systemic biologic as first-line therapy
- 3. **Nonpreferred Ustekinumab formulations:** Trial and failure, intolerance, or contraindication to ONE of the following:
 - a. Stelara
 - b. Wezlana
 - c. Yesintek

Moderately to severely active Ulcerative colitis (UC)

- 1. Diagnosis of moderately to severely active ulcerative colitis
- 2. ONE of the following:
 - a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
 - i. 6-mercaptopurine



- ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
 - iii. Azathioprine
 - iv. Corticosteroids (e.g., prednisone)
- b. Disease severity warrants systemic biologic as first-line therapy
- 2. **Nonpreferred Ustekinumab formulations:** Trial and failure, intolerance, or contraindication to ONE of the following:
 - a. Stelara
 - b. Wezlana
 - c. Yesintek

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation demonstrating member has had a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition

Limitations

1. Initial authorization and reauthorization will be granted for 24 months
2. Ustekinumab IV formulations are FDA-approved for the treatment of Crohn's disease and Ulcerative colitis and will only be authorized for one loading dose for these conditions
3. The following quantity limitations apply:

Dosage Form and Strength	Quantity Limit
130 mg IV	4 vials per 56 days
45 mg vial	1 vial per 84 days
45 mg prefilled syringe	1 prefilled syringe per 84 days
90 mg prefilled syringe	1 prefilled syringe per 56 days

References

1. Feagan BG, Sandborn WJ, Gasink C, et al. Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease. *N Engl J Med* 2016; 375:1946
2. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
4. Paul C, Puig L, Kragballe K, et al. Transition to ustekinumab in patients with moderate-to-severe psoriasis and inadequate response to methotrexate: a randomized clinical trial (TRANSIT). *Br J Dermatol* 2014; 170:425.
5. Ritchlin C, Rahman P, Kavanaugh A, et al. Efficacy and safety of the anti-IL-12/23 p40 monoclonal antibody, ustekinumab, in patients with active psoriatic arthritis despite conventional non-biological and biological anti-tumour necrosis factor therapy: 6-month and 1-year results of the phase 3, multicentre, double-blind, placebo-controlled, randomised PSUMMIT 2 trial. *Ann Rheum Dis* 2014; 73:990
6. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; November 2024.
7. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. *N Engl J Med*. 2019 Sep 26;381(13):1201-1214. doi: 10.1056/NEJMoa1900750.
8. Wezlana (ustekinumab-aub) [prescribing information]. Thousand Oaks, CA: Amgen; October 2023.
9. Yesintek (Ustekinumab-kfce) [prescribing information]. Cambridge, MA: Biocon Biologics; November 2024.



Review History

04/05/10 – Implemented

02/22/10 – Reviewed

02/28/11 – Reviewed

02/27/12 – Reviewed

02/25/13 – Reviewed

02/24/14 – Reviewed

02/23/15 – Reviewed

02/22/16 – Reviewed

02/27/17 – Updated (adopted SGM & PPD)

02/26/18 – Updated

02/20/19 – Updated

11/20/19 – Updated (added new UC indication)

09/21/2022 – Updated and reviewed for Sept P&T; updated criteria for Crohn's disease to allow for fistulizing Crohn's disease, for diagnosis of Crohn's and Ulcerative colitis - removed requirement of Humira and included any previous biologic used to treat Crohn's disease. Conventional therapy requirement was also added for Crohn's disease and Ulcerative colitis. Effective 11/1/22.

11/15/2023 – Reviewed and updated for Nov P&T; removed TB requirement. Psoriatic arthritis – removed conventional therapies and added member meets one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis – changed from 5% BSA to 3% BSA. Consolidated conventional therapies for plaque psoriasis. Separated out criteria for Crohn's disease vs. Ulcerative Colitis and added examples for each disease. Effective 1/1/2024

10/09/2024 – Reviewed and updated for October P&T. Added Wezlana to the policy. Updated reauthorization criteria to require documentation of clinical response to therapy. Effective 1/1/2025.

05/14/2025 – Reviewed and updated at May P&T. Updated criteria for Crohn's disease and ulcerative colitis to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Effective 07/1/2025.

06/11/2025 – Reviewed and updated at June P&T. Added quantity limitations to policy. Effective 07/01/2025.

09/10/2025 – Reviewed and updated at September P&T. Renamed policy "Ustekinumab Products." Added Yesintek to the policy as a preferred biosimilar. Wezlana, Stelara and Yesintek are preferred; all other Ustekinumab products are nonpreferred. Updated policy to require trial and failure with either Stelara, Wezlana or Yesintek for approval of a nonpreferred Ustekinumab product. Effective 10/15/2025.

10/08/2025 – Reviewed and updated at October P&T. Updated verbiage for nonpreferred biosimilars. Effective 10/15/2025.

