Mass General Brigham
Health Plan

Ustekinumab Products
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

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

Selarsdi (Ustekinumab-aekn), Steqeyma (Ustekinumab-stba), and Yesintek (ustekinumab-kfce) are the preferred Ustekinumab formulations. All other Ustekinumab formulations 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. 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 ALL of the following:
    a. Selarsdi
    b. Steqeyma
    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
3. Nonpreferred Ustekinumab formulations: Trial and failure, intolerance, or contraindication to ALL of the following:
    a. Selarsdi
    b. Steqeyma
    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. **SC injection:** Member meets ONE of the following:
    a. Subcutaneous formulation will be used as maintenance therapy following IV induction
    b. Member has received the IV induction doses and is transitioning to maintenance therapy
4. Nonpreferred Ustekinumab formulations: Trial and failure, intolerance, or contraindication to ALL of the following:
    a. Selarsdi
    b. Steqeyma
    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

3. **SC injection:** Member meets ONE of the following:
   a. Subcutaneous formulation will be used as maintenance therapy following IV induction
   b. Member has received the IV induction doses and is transitioning to maintenance therapy
4. Nonpreferred Ustekinumab formulations: Trial and failure, intolerance, or contraindication to ALL of the following:
   a. Selarsdi
   b. Steqeyma
   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
2. Nonpreferred Ustekinumab formulations: Trial and failure, intolerance, or contraindication to ALL of the following:
   a. Selarsdi
   b. Steqeyma
   c. Yesintek

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	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-aaub) [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. 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 11/01/2025.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to reflect that Selarsdi and Steqeyma are preferred and all other Ustekinumab products are nonpreferred. Updated criteria for nonpreferred ustekinumab products to require trial and failure with all preferred agents (Selarsdi, Steqeyma, and Yesintek). Updated criteria for ulcerative colitis and Crohn's disease to require induction with the IV formulation for approval of the subcutaneous formulation. Updated reauthorization criteria to require trial and failure with all preferred agents

for approval of nonpreferred formulations. Updated policy to indicate that it no longer applies to medical benefit. Effective 01/01/2026.