Mass General Brigham
Health Plan

Stelara (ustekinumab)
Wezlana (ustekinumab)
Effective 01/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
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 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	Wezlana IV is only available through the medical benefit		

Overview

Stelara (ustekinumab) and Wezlana (ustekinumab-aaub) are human interleukin-12 and -23 antagonists 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

Stelara and Wezlana are 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

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.

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

Moderately to severely active Crohn's disease (CD)

1. Diagnosis of moderately to severely active Crohn's disease
2. ONE of the following:
    a. Frequent diarrhea and abdominal pain
    b. At least 10% weight loss
    c. Complications such as obstruction, fever, abdominal mass
    d. Abnormal lab values (e.g., C-reactive protein [CRP])
    e. CD Activity Index (CDAI) greater than 220
    f. Fistulizing Crohn's disease
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine
    b. Azathioprine
    c. Corticosteroids (e.g., prednisone)
    d. Methotrexate

Moderately to severely active Ulcerative colitis (UC)

1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
    a. Greater than 6 stools per day
    b. Frequent blood in stools
    c. Frequent urgency
    d. Presence of ulcers
    e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
    f. Dependent on, or refractory to, corticosteroids
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine
    b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
    c. Azathioprine
    d. Corticosteroids (e.g., prednisone)

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. Stelara IV and Wezlana IV are FDA-approved for the treatment of Crohn's disease and Ulcerative and will only be authorized for one loading dose for these conditions

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.; March 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.

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.