Mass General Brigham
Health Plan

Stelara (ustekinumab)
Effective 01/02/2024

Plan	☒ MassHealth ☐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 and 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	Stelara 130 mg/26 mL vial is available through the medical benefit. All other strengths or formulations are available through both pharmacy and medical benefits.		

Overview
Ustekinumab in a monoclonal antibody that binds to and interferes with proinflammatory cytokines, interleukin (IL)-12 and IL-23. Ustekinumab also interferes with the expression of monocyte chemotactic protein-1 (MCP-1), tumor necrosis factor-alpha, interferon-inducible protein-10 and interleukin (IL)-8 resulting in reduction of these proinflammatory signalers.

Drugs that require PA
Stelara (ustekinumab 45 mg/0.5 mL prefilled syringe, 90 mg/mL prefilled syringe, 45 mg/0.5 mL vial)
Stelara (ustekinumab 130 mg/26 mL vial) [MB]

MB - Medical Benefit. This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting.

FDA-Approved Indications
- Moderate to severe plaque psoriasis
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active Ulcerative colitis (UC)

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Stelara excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met:

Psoriatic arthritis

ALL of the following:

1. Diagnosis of psoriatic arthritis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
    b. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
3. Appropriate dosing

Moderate to severe plaque psoriasis

ALL of the following:

1. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy or contraindication to **ALL** conventional therapies (see appendix B)
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing

Moderate to severe Crohn's disease

ALL of the following:

1. Diagnosis of moderate to severe Crohn's disease
2. Appropriate dosing

Moderate to severe ulcerative colitis

ALL of the following:

1. Diagnosis of moderate to severe ulcerative colitis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for ulcerative colitis
    b. Contraindication to **ALL** biologic DMARDs that are FDA-approved for ulcerative colitis
3. Appropriate dosing

<u>Off-Label Indications</u>

Fistulizing Crohn's disease

ALL of the following:

1. Diagnosis of fistulizing Crohn's disease
2. Physician attestation of inadequate response or adverse reaction to **ONE** anti-TNF agent or a contraindication to **ALL** anti-TNF agents
3. One of the following appropriate dosing:
    a. Members ≤55 kg: 260 mg (2 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every eight weeks
    b. Members 55-85 kg: 390 mg (3 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every eight weeks
    c. Members >85 kg: 520 mg (4 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every eight weeks

Moderate to severe hidradenitis suppurativa
ALL of the following:

1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II and Hurley Stage III disease)
2. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)
3. Inadequate response, adverse reaction, or contraindication to Humira (adalimumab)
4. **If reviewing under Pharmacy Benefit:** Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following: unbranded infliximab, Kineret® (anakinra), Remicade® (infliximab), Avsola® (infliximab-axxq), Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda)

Pityriasis rubra pilaris (PRP)
ALL of the following:

1. Diagnosis of pityriasis rubra pilaris
2. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** topical corticosteroid or contraindication to **ALL** topical corticosteroids

Synovitis-acne-pustulosis-hyperostosis-osteitis syndrome (SAPHO)
ALL of the following:

1. Diagnosis of SAPHO
2. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** NSAID or contraindication to **ALL** NSAIDs
3. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids

New members currently stable on Stelara® can be approved without documentation of failed trials with the conventional therapies.

Continuation of Therapy
Resubmission by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for:
    a. Plaque Psoriasis and off label indications: 3 months
    b. All other diagnosis: 6 months
2. Reauthorizations will be granted for 12 months

Appendix:
Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

More Frequent/High Doses

Requests for more frequent or higher doses of injectable biologics may be approved if **ALL** of the following is provided:

1. Documentation of severe disease
2. Documentation partial response to FDA-approved dosing of current biologic therapy
3. Documentation of specialist consult for the requested indication

Requests for Concomitant Biologic Therapies

Requests for any of the combinations (ustekinumab with adalimumab or ustekinumab with infliximab) for Crohn's disease or ulcerative colitis may be approved if the following criteria are met:

1. Documented partial response to current therapy
2. Prescriber is a specialist or specialist consult is provided
3. Member meets approval criteria for the individual agents

References

1. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; December 2020.
2. 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.
3. 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.
4. 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
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. 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.
7. Hendrickson BA, Gokhale R, Cho JH. Clinical aspects and pathophysiology of inflammatory bowel disease. *Clin Microbiol Rev*. 2002;15(1):79-94
8. Crohn's & Colitis Foundation of America. Inflammatory bowel disease and irritable bowel syndrome: similarities and differences. www.crohnscolitisfoundation.org/assets/pdfs/ibd-and-irritable-bowel.pdf. Published July 2014. Accessed July 7, 2019.
9. Molodecky NA, Soon IS, Rabi DM, et al. Increasing incidence and prevalence of the inflammatory bowel diseases with time, based on systematic review. *Gastroenterology*. 2012;142(1):46-54
10. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG clinical guideline: Ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114(3)384-413
11. Danese S, Allex M, van Bodegraven AA, et al. Unmet medical needs in ulcerative colitis: an expert group consensus. *Digestive Diseases*. 2019;37(4)266-283

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 & Step)
02/26/18 – Updated
03/01/18 – Updated (Adopted MH RS)
02/20/19 – Updated
11/20/19 – Updated (added new UC indication)
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
06/22/2022 - Reviewed and updated for June P&T; matched MH UPPL. Approval criteria in Crohn's disease was updated to remove step through one other biologic DMARD. Continuation of therapy language was updated. New off label indication was added to appendix for fistulizing Crohn's disease. Added to appendix More Frequent/High Doses section. Appendix Dosing section was updated. Updated references. Effective 08/01/2022.
01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members. Off-label indications added for: fistulizing Crohn's disease, HS, PRP, SAPHO. Added appendix for requests for concomitant biologic therapies. Effective 3/1/23.
06/14/23 – Reviewed and updated for P&T. Separated out HS criteria and removed preferred product requirement (left Humira trial alone as its considered first line in practice) for requests through MB. Effective 6/30/23
09/13/23 – Reviewed and updated for P&T. Removed Dosing Appendix. No clinical changes. Effective 10/2/23
12/13/23 – Reviewed and updated for P&T. Stelara (ustekinumab 130 mg/26 mL vial) preferred status was removed. Formatting updates. No clinical changes. Effective 1/2/24