Stelara (ustekinumab)
Effective January 1, 2020

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

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

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

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines
Approval may be granted for members who meet the following diagnosis specific criteria:

Psoriatic arthritis (PsA):
1. Member is at least 18 years of age **AND**
2. Member has a diagnosis of PsA **AND**
3. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication **AND**

4. Dosing is appropriate (see appendix A)

Moderate-severe plaque psoriasis:

1. Member has a diagnosis of moderate-severe plaque psoriasis **AND**
2. Member is at least 12 years of age **AND**
3. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least TWO conventional therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
        i. 1 topical agent + 1 systemic agent
        ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
        iii. 1 systemic agent + 1 phototherapy
        iv. 2 systemic agents
    b. Contraindication to ALL conventional therapies
        i. Topical agents
        ii. Phototherapy
        iii. Systemic agents
    c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis **AND**
4. Dosing is appropriate (see appendix A)

Moderate-severe Crohn's disease:

1. Member is at least 18 years of age **AND**
2. Member has a diagnosis of moderate- severe Crohn's disease **AND**
3. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
        i. Aminosalicylate
        ii. Antibiotic
        iii. Corticosteroid
        iv. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate **AND**
4. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for Crohn's disease
    b. Contraindication to ALL biologic DMARDs that are FDA-approved for Crohn's disease
5. Dosing is appropriate (see appendix A)

**If a request documents severe disease, a trial of an oral immunomodulator may be bypassed*

Ulcerative colitis

1. Member is at least 18 years of age **AND**
2. Member has a diagnosis of Ulcerative Colitis **AND**
3. Member has had an adverse reaction to one biologic DMARD that is FDA-approved for ulcerative colitis; **OR**
4. Member has had an inadequate response, adverse reaction, or contraindication to all of the following:
    a. an aminosalicylate; **AND**

b. a corticosteroid; **AND**
c. an immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate).

Continuation of Therapy
Reauthorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Stelara as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
    a. Note: Members who have received Stelara or any other biologic DMARD or targeted synthetic DMARD (e.g. Xeljanz) are exempt from requirements related to TB screening in this Policy.
2. Stelara for intravenous administration is FDA-approved for the treatment of Crohn's disease and Ulcerative and will only be authorized for one loading dose for this condition

Appendix A:

Stelara® (ustekinumab)	**Crohn's Disease:** Patients ≤ 55 kg 260 mg (2 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every 8 weeks Patients 55-85 kg 390 mg (3 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every 8 weeks Patients > 85 kg 520 mg (4 vials) IV, followed by 90 mg SQ after initial dose then 90 mg SQ every 8 weeks **Plaque Psoriasis:** Patients ≤ 100 kg (220 lbs.) 45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks Patients > 100 kg (220 lbs.) * 90 mg initially (week 0), at week 4, followed by 90 mg every 12 weeks **Psoriatic Arthritis:** 45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks **Co-existent Plaque Psoriasis AND Psoriatic Arthritis in Patient >100 kg (220 lbs.):** 90 mg initially (week 0), at week 4, followed by 90 mg every 12 weeks **Ulcerative Colitis:** A single intravenous infusion using weight-based dosing: Weight Range (kilogram) Recommended Dosage for patients up to 55 kg 260 mg (2 vials) Patients greater than 55 kg to 85 kg 390 mg (3 vials)

	Patients greater than 85 kg 520 mg (4 vials), Followed by a subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, then 90mg every 8 weeks thereafter

References

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; © 2012, 2016, 2019 Janssen Pharmaceutical Companies
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)

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