Stelara (ustekinumab)
Effective 11/01/2022

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:

Moderate to severe plaque psoriasis
Authorization may be granted 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 program

OR

Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met, and documentation has been provided:

1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
2. Member meets ONE of the following criteria:
    a. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
        i. 1 topical agent + 1 systemic agent (methotrexate, acitretin, or cyclosporine)
        ii. 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
        iii. 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
        iv. 2 systemic agents
    b. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). (See Appendix A*)*
    c. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Active psoriatic arthritis (PsA)
Authorization may be granted 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 program

OR

Authorization may be granted when all of the following criteria is met, and documentation has been provided:

1. The member is diagnosed with active PsA
2. Member meets ONE of the following:
    a. The member has had an intolerance or inadequate response (after at least 3 months of treatment) with methotrexate or leflunomide
    b. The member has a contraindication to BOTH methotrexate and leflunomide and has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Moderately to severely active Crohn's disease (CD)
Authorization may be granted 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 program

OR

Authorization may be granted when ONE of the following criteria is met, and documentation of the following has been provided:

1. The member has previously received a biologic indicated for Crohn's disease
2. The member has had an inadequate response, intolerance, or contraindication to at least one conventional therapy option (see Appendix B).
3. The member has fistulizing Crohn's disease

Moderately to severely active Ulcerative colitis (UC)
Authorization may be granted 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 program

OR

Authorization may be granted when ONE of the following criteria is met, and documentation of the following has been provided:

1. The member has previously received a biologic indicated for moderately to severely active Ulcerative Colitis

2. The member has had an inadequate response, intolerance, or contraindication to at least one conventional therapy option (see Appendix C).

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

Appendices

Appendix A

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix B

Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
    a. Oral budesonide, oral mesalamine
    b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
    a. Prednisone, methylprednisolone intravenously (IV)
    b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission:
    a. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission:

a. Azathioprine, mercaptopurine
b. Alternative: methotrexate IM

Appendix C
Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)
    b. Rectal mesalamine (e.g., Canasa, Rowasa)
    c. Alternatives: azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
    a. Oral mesalamine, rectal mesalamine
    b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
    a. Sulfasalazine
4. Severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: sulfasalazine
5. Pouchitis: rectal mesalamine

References

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; Oct.2019
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. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med. 2019 Sep 26;381(13):1201-1214. doi: 10.1056/NEJMoa1900750.

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 11/01/2022

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