Stelara (ustekinumab)
Effective January 1, 2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐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

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)
5. Moderate to severe hidradenitis suppurativa (HS) – off label indication

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners 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, and documentation is provided:

Psoriatic Arthritis (PsA)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis

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

NOTE: DMARD trial is not required in members with active psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs

Moderate to Severe Plaque Psoriasis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy (see appendix B)
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Contraindication to **ALL** conventional therapies:
        i. topical agents
        ii. phototherapy
        iii. systemic agents
    c. 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
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
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 Crohn's disease
    b. Contraindication to **ALL** biologic DMARDs that are FDA-approved for Crohn's disease
3. Appropriate dosing

Moderate-to-severe Ulcerative colitis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
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

Continuation of Therapy
Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, an approved indication and appropriate dosing.

Limitations

1. Initial approvals will be granted for:
    a. Plaque Psoriasis 3 months.
    b. All other diagnosis: 6 months.
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Stelara Inj 5mg/mL	4 vials per 56 days
Stelara Inj 45mg/0.5mL	1 unit per 12 weeks
Stelara Inj 90mg/mL	1 unit per 8 weeks

Appendix:

Appendix A: Dosing

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

Appendix B. 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)

Appendix C: Off-Label Indications

Moderate to severe hidradenitis suppurativa (HS)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II and Hurley Stage III disease)
2. Paid claims or physician documented inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)
3. Paid claims or physician documented inadequate response, adverse reaction or contraindication to Humira® (adalimumab)
4. Dosing of Stelara: 45 to 90mg every 12 weeks

References

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

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