Stelara (ustekinumab)
Effective 03/01/2023

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	Stelara IV injection is available through the medical benefit.		

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
- 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, and documentation is provided:

Psoriatic arthritis
Prescriber provides documentation of **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 (see Appendix for frequent or higher doses)

Moderate to severe plaque psoriasis
Prescriber provides documentation of **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 (see Appendix for frequent or higher doses)

Moderate to severe Crohn's disease
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of moderate to severe Crohn's disease
2. Appropriate dosing (see Appendix for frequent or higher doses)

Moderate to severe ulcerative colitis
Prescriber provides documentation of **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 (see Appendix for frequent or higher doses)

Off-Label Indications
Fistulizing Crohn's disease
Prescriber provides documentation of **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. Appropriate dosing

Moderate to severe hidradenitis suppurativa
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 within 6 months or physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)

3. **BOTH** of the following:
    a. Paid claims or physician documentation of inadequate response, adverse reaction, or contraindication to Humira® (adalimumab)
    b. Paid claims or physician documentation of 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)
Prescriber provides documentation of **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)
Prescriber provides documentation of **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 and request can be recertified if dosing is appropriate.

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
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 A: Dosing

Stelara® (ustekinumab)	**Crohn's Disease and Ulcerative Colitis** Adult Patients ≤ 55 kg 260 mg (2 vials) IV, followed by 90 mg SQ given 8 weeks after initial IV dose then 90 mg SQ every 8 weeks Adult Patients 55-85 kg

	390 mg (3 vials) IV, followed by 90 mg SQ given 8 weeks after initial IV dose then 90 mg SQ every 8 weeks Adult Patients > 85 kg 520 mg (4 vials) IV, followed by 90 mg SQ given 8 weeks after initial IV dose then 90 mg SQ every 8 weeks **Plaque Psoriasis:** Pediatric patients < 60 kg (132 lbs.) 0.75 mg/kg initially (week 0), at week 4, followed by 90 mg every 12 weeks Adult Patients ≤ 100 kg (220 lbs.) and pediatric patients (ages 6-17) 60-100 kg 45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks Adult and pediatric patients > 100 kg (220 lbs.) 90 mg initially (week 0), at week 4, followed by 90 mg every 12 weeks **Psoriatic Arthritis:** Adult patients 45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks **Co-existent Plaque Psoriasis AND Psoriatic Arthritis in Patients > 100 kg (220 lbs.):** 90 mg initially (week 0), at week 4, followed by 90 mg every 12 weeks

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: 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

Appendix D: 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:

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

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

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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.
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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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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.

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