

**Stelara (ustekinumab)
Effective 08/01/2022**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> 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 is 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 chemoattractant 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

- Moderate to severe plaque psoriasis
- Active psoriatic arthritis
- Moderately to severely active Crohn’s disease
- Moderately to severely active Ulcerative colitis (UC)
- Moderate to severe hidradenitis suppurativa (HS) – off label indication
- Fistulizing Crohn’s disease – 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 (see Appendix for frequent or higher doses)

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 (see Appendix for frequent or higher doses)

Moderate to severe Crohn's disease

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

1. Appropriate diagnosis
2. Appropriate dosing (see Appendix for frequent or higher doses)

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 (see Appendix for frequent or higher doses)

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

Appendices

Appendix A: Dosing

Stelara® (ustekinumab)	<p>Crohn’s Disease and Ulcerative Colitis</p> <p><u>Adult Patients ≤ 55 kg</u> 260 mg (2 vials) IV, followed by 90 mg SQ given 8 weeks after initial IV dose then 90 mg SQ every 8 weeks</p> <p><u>Adult Patients 55-85 kg</u> 390 mg (3 vials) IV, followed by 90 mg SQ given 8 weeks after initial IV dose then 90 mg SQ every 8 weeks</p> <p><u>Adult Patients > 85 kg</u> 520 mg (4 vials) IV, followed by 90 mg SQ given 8 weeks after initial IV dose then 90 mg SQ every 8 weeks</p> <p>Plaque Psoriasis:</p> <p><u>Pediatric patients < 60 kg (132 lbs.)</u> 0.75 mg/kg initially (week 0), at week 4, followed by 90 mg every 12 weeks</p> <p><u>Adult Patients ≤ 100 kg (220 lbs.) and pediatric patients (ages 6-17) 60-100 kg</u> 45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks</p> <p><u>Adult and pediatric patients > 100 kg (220 lbs.)</u> 90 mg initially (week 0), at week 4, followed by 90 mg every 12 weeks</p> <p>Psoriatic Arthritis:</p> <p><u>Adult patients</u> 45 mg initially (week 0), at week 4, followed by 45 mg every 12 weeks</p> <p>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</p>
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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)
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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: 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. **BOTH** of the following:
 - a. Paid claims or physician documented inadequate response, adverse reaction or contraindication to Humira® (adalimumab)
 - b. Paid claims or physician documented inadequate response, adverse reaction to ONE of the following or contraindication to ALL of the following:
 - i. Kineret® (anakinra)
 - ii. Remicade® (infliximab)
 - iii. Avsola® (infliximab-axxq)
 - iv. Inflectra® (infliximab-dyyb)
 - v. Renflexis® (infliximab-abda)
4. Dosing of Stelara: 45 to 90 mg at week 0 and 4, then every 12 weeks, OR 45 to 90 mg every 12 weeks

Fistulizing Crohn’s Disease

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

1. Appropriate diagnosis
2. Physician documented of an inadequate response or adverse reaction to **ONE** anti-TNF agent or a contraindication to **ALL** anti-TNF agents
3. Appropriate dose (refer to recommended dosing in Crohn’s Disease and Ulcerative Colitis as outlined in the Dosing section)

References

1. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; December 2020.
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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
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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
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11. Danese S, Alex 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.

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