Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Ustekinumab Subcutaneous Products

Effective: November 1, 2026

Guideline Type	☒ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Ustekinumab is a human interleukin-12 and -23 antagonist indicated for:

Disease State	
Crohn's Disease	X
Plaque Psoriasis	X
Psoriatic Arthritis	X
Ulcerative Colitis	X

Ustekinumab Subcutaneous products in this Medical Necessity Guideline include: Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Ustekinumab, Ustekinumab-aauz, Ustekinumab-aekn, Ustekinumab-ttwe, and Wezlana.

Yesintek and Starjemza are the preferred Ustekinumab Subcutaneous products and require prior authorization. See Yesintek and Starjemza Subcutaneous Medical Necessity Guideline.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab-aauz, Ustekinumab-aekn, Ustekinumab-ttwe, and Wezlana for Members when **ALL** of the following criteria are met:

Crohn's Disease

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active Crohn's disease

AND

2. Patient is at least 2 years of age or older

AND

3. Prescribed by a gastroenterologist

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: document drugs, dates, and duration of trials)*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation of history of failure to at least **two (2)** of the following medications from each of the following therapeutic categories (only one medication is required if only one is available for a listed therapeutic category), unless contraindicated

(*Note: document drugs, dates, and duration of trials*):

a. Interleukin Antagonists: Omvoh, Skyrizi, Tremfya
b. Janus Kinase Inhibitors: Rinvoq (upadacitinib)
c. Tumor Necrosis Factors: Cimzia, Simlandi

AND

6. Documentation of history of failure to a minimum three (3) month supply of Yesintek, unless contraindicated (*Note: document date and duration of trial)*

AND

7. Documentation of history of failure to a minimum three (3) month supply of Starjemza, unless contraindicated (*Note: document date and duration of trial)*

AND

8. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active Crohn's disease

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Plaque Psoriasis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severe plaque psoriasis

AND

2. Documentation of **one (1)** of the following:

a. Geater than or equal to 3% body surface area involvement
b. Severe scalp psoriasis
c. Palmoplantar, facial, or genital involvement

AND

3. Patient is at least 6 years of age or older

AND

4. Prescribed by a dermatologist

AND

5. Documentation of failure to a minimum three (3) month supply of at least **one (1)** of the following traditional systemic agents, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine, acitretin, or phototherapy (Note: document drug, date and duration of trial*)*

AND

6. Documentation of history of failure to **two (2)** of the listed medications from each of the following therapeutic categories (only one medication is required if only one is available for a listed therapeutic category), unless contraindicated *(Note: document drugs, dates and duration of trials):*

a. Interleukin Antagonists: Bimzelx, Skyrizi, Taltz, Tremfya
b. Phosphodiesterase 4 inhibitors: Otezla (apremilast)
c. Tumor Necrosis Factors: Cimzia, Enbel, Simlandi

AND

7. Documentation of history of failure to a minimum three (3) month supply of Yesintek, unless contraindicated (*Note: document date and duration of trial)*

AND

8. Documentation of history of failure to a minimum three (3) month supply of Starjemza, unless contraindicated (*Note:*

document date and duration of trial)

AND

9. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of moderately to severe plaque psoriasis

AND

3. Patient is at least 6 years of age or older

AND

4. Prescribed by a dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined as reduction in body surface area affected by plaque psoriasis from baseline

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of plaque psoriasis such as itching, redness, flaking, scaling, burning, cracking, or pain

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Psoriatic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active psoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

AND

3. Patient Is at least 6 years of age or older

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Documentation of failure to a minimum three (3) month supply of at least **one (1)** disease-modifying anti-rheumatic drug (e.g., methotrexate, sulfasalazine, cyclosporine), unless contraindicated or clinically significant adverse effects are experienced (*Note: document drug, date and duration of trial*)

AND

6. Documentation of history of failure to **two (2)** of the listed medications from each of the following therapeutic categories (only one medication is required if only one is available for a listed therapeutic category), unless contraindicated *(Note: document drugs, dates and duration of trials*):
    a. Interleukin Antagonists: Bimzelx, Skyrizi, Taltz, Tremfya
    b. Janus Kinase Inhibitors: Rinvoq (upadacitinib), Xeljanz (tofacitinib)
    c. Phosphodiesterase 4 inhibitors: Otezla (apremilast)
    d. Selective T Cell Stimulators: Orencia
    e. Tumor Necrosis Factors: Cimzia, Enbrel, Simlandi, Simponi

AND

7. Documentation of history of failure to a minimum three (3) month supply of Yesintek, unless contraindicated (*Note: document date and duration of trial)*

AND

8. Documentation of history of failure to a minimum three (3) month supply of Starjemza, unless contraindicated (*Note: document date and duration of trial)*

AND

9. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of active psoriatic arthritis

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined improvement from baseline in at least **one (1)** of the following:
    a. Body surface area affected by psoriatic arthritis
    b. Total active (swollen and tender) joint count

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of psoriatic arthritis such as joint pain, morning stiffness, fatigue, joint or tendon sheath swelling

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Patient is at least 2 years of age or older

AND

3. Prescribed by a gastroenterologist

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial):*
    a. Corticosteroid
    b. 5- aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation of history of failure to at least **two (2)** of the following medications from each of the following therapeutic categories (only one medication is required if only one is available for a listed therapeutic category), unless contraindicated (*Note: document drugs, dates, and duration of trials*):
    a. Interleukin Antagonists: Omvoh, Skyrizi, Tremfya
    b. Janus Kinase Inhibitors: Rinvoq (upadacitinib), Xeljanz (tofacitinib)
    c. Sphingosine 1-phosphate receptor modulator: Zeposia
    d. Tumor Necrosis Factors: Simlandi, Simponi

AND

6. Documentation of history of failure to a minimum three (3) month supply of Yesintek, unless contraindicated (*Note: document date and duration of trial)*

AND

7. Documentation of history of failure to a minimum three (3) month supply of Starjemza, unless contraindicated (*Note: document date and duration of trial)*

AND

8. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

3. Patient is at least 2 years of age or older

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Stelara, Ustekinumab Subcutaneous

In addition to the coverage criteria above for the requested indication

1. Documentation of history of failure to Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab-aauz, Ustekinumab-aekn, Ustekinumab-ttwe, and Wezlana, unless contraindicated *(Note: document drugs, dates and duration of trials)*

Limitations

1. Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria.
2. For Crohn's disease and ulcerative colitis, authorizations will be provided in 12-month intervals. A patient who has received less than 12 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
3. For plaque psoriasis and psoriatic arthritis, initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals. A Member who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
4. Members new to the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

1. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech; August 2026.
2. Imuldosa (ustekinumab-srlf) [prescribing information]. Raleigh, North Carolina: Accord BioPharma, Inc; December 2025.
3. Otulfi (ustekinumab-aauz) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; February 2026.
4. Pyzchiva (ustekinumab-ttwe) [prescribing information]. Princeton, New Jersey: Sandoz Inc.; March 2026.
5. Selarsdi (ustekinumab-aekn) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals; December 2025.
6. Steqeyma (ustekinumab-stba) [prescribing information]. Jersey City, New Jersey: Celltrion USA, Inc.; April 2026.
7. Wezlana (ustekinumab-auub) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; February 2026.
8. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
9. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
10. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
11. Singh S, Loftus EV, Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Gastroenterology. 2024 Dec;167(7):1307-1343.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee

Subsequent endorsement date(s) and changes made:

- December 12, 2023: No changes
- November 12, 2024: No changes (eff 11/12/24)
- June 10, 2025: Updated title of Medical Necessity Guideline from Stelara (ustekinumab) Subcutaneous to Ustekinumab

Subcutaneous Products. Added Pyzchiva, Selarsdi, Steqeyma, and Wezlana to the Medical Necessity Guideline. Updated coverage criteria to require a trial and failure with at least two preferred products from available mechanism of actions that have shared indications, or a contraindication to them all. Added Documented previous failure of or clinical inappropriateness of treatment with Yesintek. Added additional requirements for Stelara and Ustekinumab to require a trial and failure of or clinical inappropriateness of treatment with available non-preferred ustekinumab biosimilars (eff 9/1/25).

- August 12, 2025: Added Imuldosa to the Medical Necessity Guideline (eff 9/1/25).
- October 14, 2025: Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. Added a minimum of a three month supply of Yesintek prior to approval of Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab, Ustekinumab-aekn, Ustekinumab-ttwe, and Wezlana. For plaque psoriasis and psoriatic arthritis, initial approvals limited to 6 months with annual reauthorization coverage criteria added. For plaque psoriasis and psoriatic arthritis, added disease severity requirements. For plaque psoriasis, added prerequisites and updated prerequisite language. For Crohn's disease and ulcerative colitis, approvals limited to 12 months with reauthorization coverage criteria added, added prerequisites, and updated prerequisite language (eff 1/1/26).
- December 9, 2025: Replaced Humira with Simlandi as Simlandi is the preferred adalimumab product (eff 3/1/26).
- June 9, 2026: Added Starjemza and Ustekinumab-aauz to the Medical Necessity Guideline. To support the updated ustekinumab strategy (Yesintek and Starjemza are the preferred ustekinumab products), added a minimum of a three month supply of Starjemza prior to approval of Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab-aauz, Ustekinumab-aekn, Ustekinumab-ttwe, and Wezlana. Updated age requirements in Crohn’s disease to at least 2 years of age. Administrative update to the limitation statement to include members initiated on the requested medication by self-paying for the medication directly do not qualify for established clinical response and should be reviewed against initial approval criteria. Administrative update to remove CareLink from Medical Necessity Guideline template. (eff 7/1/26).
- October 13, 2026: Updated age requirements in ulcerative colitis to at least 2 years of age. Administrative edit to include small-molecule chemical entity names. (eff 11/1/26)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.