Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:

Yesintek (ustekinumab-kfce) and Starjemza (ustekinumab-hmny) Subcutaneous

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

Yesintek (ustekinumab-kfce) and **Starjemza (ustekinumab-hmny)** are interleukin-12 and -23 antagonists indicated for:

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

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Yesintek (ustekinumab-kfce) and Starjemza (ustekinumab-hmny) Subcutaneous 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-aminosalycyclate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. 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. Greater 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 30-day supply (14-day supply for topical corticosteroids) to **one (1)** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced: corticosteroid, vitamin D analog, tazarotene, calcineurin inhibitor *(Note: document drug, date and duration of trial)*

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

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 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 6 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-aminosalycyclate
   c. 6-mercaptopurine
   d. Methotrexate

AND

5. 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

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. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.
3. 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.
4. 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.
5. Members new to the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

1. Yesintek (ustekinumab-kfce) [prescribing information]. Cambridge, MA: Biocon Biologics Inc; January 2026.
2. 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.
3. 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.
4. 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.
5. 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

June 10, 2025: Reviewed by the Pharmacy & Therapeutics Committee (eff 9/1/25).

- October 14, 2025: October 14, 2025: Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. 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, updated Initial Authorization Criteria prerequisite language (no change in prerequisites) and removed previous treatment with a biologic agent indicated for the requested use and Yesintek stability language. For Crohn's disease and ulcerative colitis, approvals limited to 12 months with reauthorization coverage criteria added, updated Initial Authorization Criteria prerequisite language (no change in prerequisites), and removed previous treatment with a biologic agent indicated for the requested use and Yesintek stability language (eff 1/1/26)
- June 9, 2026: Updated title of Medical Necessity Guideline from Yesintek (ustekinumab-kfce) Subcutaneous to Yesintek (ustekinumab-kfce) and Starjemza (ustekinumab-hmny) Subcutaneous to support the updated ustekinumab strategy – Yesintek and Starjemza are the preferred ustekinumab products. 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. (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.