Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Zeposia (ozanimod)**

Effective: July 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

Zeposia (ozanimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of:

- **Multiple Sclerosis**
  Relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- **Ulcerative Colitis**
  Moderately to severely active ulcerative colitis in adults

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Zeposia for Members when **ALL** of the following criteria are met:

Multiple Sclerosis

Initial Authorization Criteria

1. Documented diagnosis of relapsing multiple sclerosis

AND

2. Patient is at least 18 years of age or older

AND

3. 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 relapsing multiple sclerosis

AND

3. Patient is at least 18 years of age or older

AND

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

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

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Patient is at least 18 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 of history of failure to **two (2)** of the following, unless contraindicated for clinically significant adverse effects are experienced *(Note: document drugs, dates, and duration of trials):*
    a. Omvoh
    b. Rinvoq
    c. Simlandi
    d. Simponi
    e. Skyrizi
    f. Tremfya
    g. Xeljanz
    h. Yesintek or Starjemza

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 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 18 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

- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
- 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.
- Members new to the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

1. Zeposia (ozanimod) [prescribing information]. Summit, NJ: Celgene Corporation; August 2024.
2. 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
- September 10, 2024: Added Skyrizi as a prerequisite option based on the supplemental indication in ulcerative colitis (eff 10/1/24).
- December 2024: Added Omvoh as a prerequisite option for ulcerative colitis (eff 1/1/25).
- June 10, 2025: Updated prerequisites for Plaque psoriasis and Psoriatic arthritis to support the update ustekinumab strategy – Yesintek is the preferred ustekinumab product (eff 9/1/25).
- October 14, 2025: Approvals limited to 12 months with annual reauthorization coverage criteria added. Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. For ulcerative colitis, added non-biologic prerequisites to Initial Authorization Criteria and updated biologic prerequisite language (no change in prerequisites). For multiple sclerosis, added age requirements (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 Tremfya and Starjemza as prerequisite options for ulcerative colitis. Administrative update to remove CareLink from Medical Necessity Guideline template. (eff 7/1/26).

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.