Pharmacy Medical Necessity Guidelines:
Zeposia® (ozanimod)

Effective: October 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617-673-0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-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

COVERAGE GUIDELINES

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

Multiple Sclerosis

1. Documented diagnosis of **one (1)** of the following:
   a. Clinically isolated syndrome
   b. Relapse-remitting multiple sclerosis
   c. Active secondary-progressive multiple sclerosis

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. The Member is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. The Member is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting) , history of bowel resections, or recent hospitalization for the disease
   b. documentation the Member has demonstrated an inadequate response to an appropriate trial with at least two of the following or the provider has indicated clinical inappropriateness of all of the following:
      i. Corticosteroids (e.g., prednisone)
      ii. 5-Aminosalicyclates (e.g., sulfasalazine)
      iii. 6-mercaptopurine and/or azathioprine
      iv. Methotrexate

AND

5. Documentation of **one (1)** of the following:
   a. The Member has tried and failed treatment with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, Simponi, or Starjemza (ustekinumab-hmny)
   b. The Member is new to the plan and stable on Zeposia for the treatment of ulcerative colitis and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

LIMITATIONS

None

CODES

None

REFERENCES

1. Zeposia (ozanimod) [prescribing information]. Summit, NJ: Celegene Corporation; June 2024.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

- December 12, 2023: No changes
- September 10, 2024: Updated biologic prerequisite options for ulcerative colitis from Humira to Adalimumab-adbm, Adalimumab-fkjp, Hadlima, Simponi, or Stelara (eff 10/1/24).
- September 9, 2025: No changes
- September 15, 2026: Updated coverage criteria for ulcerative colitis to list Starjemza (ustekinumab-hmny) instead of Stelara for biologic prerequisite options (eff 10/1/26).

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.

Provider Services