Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Veopoz™ (pozelimab-bbfg)

Effective: January 13, 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

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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

Veopoz (pozelimab-bbfg) is a complement inhibitor indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

Clinical Guideline Coverage Criteria

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

Initial Authorization Criteria

1. Documented diagnosis of complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease

AND

2. Documentation of genetic testing confirming the presence of the CD55 loss-of-function variant

AND

3. Patient is at least 1 year of age or older

AND

4. Prescribed by or in consultation with a hematologist, gastroenterologist, or a physician who specializes in rare genetic hematologic diseases

Reauthorization Criteria

1. Documented diagnosis of complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease

AND

2. Documentation of genetic testing confirming the presence of the CD55 loss-of-function variant

AND

3. Patient is at least 1 year of age or older

AND

4. Prescribed by or in consultation with a hematologist, gastroenterologist, or a physician who specializes in rare genetic

hematologic diseases

AND

5. Documentation the patient has experienced a therapeutic response defined as **one (1)** of the following:
    a. Improvement or no worsening in clinical symptoms of CHAPLE (e.g., abdominal pain, bowel movement frequency, facial and peripheral edema severity)
    b. Increase or stabilization of albumin and IgG concentrations
    c. Increase in growth percentiles

Limitations

1. Initial approval of Veopoz will be authorized for six (6) months. Reauthorization of Veopoz will be provided in 12-month intervals.
2. Patients new to the plan stable on Veopoz should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9376	Injection, pozelimab-bbfg, 1 mg

References

1. Veopoz (pozelimab-bbfg) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2025.
2. Ozen A, et al. Broadly effective metabolic and immune recovery with C5 inhibition in CHAPLE disease. Nat Immunol. 2021;22(2):128–139.
3. Ozen A, et al. CD55 deficiency, early-onset protein-losing enteropathy, and thrombosis. N Engl J Med. 2017;377(1):52–61.
4. Ozen A, et al; Pozelimab CHAPLE Working Group. A phase 2/3 study evaluating the efficacy and safety of pozelimab in patients with CD55 deficiency with hyperactivation of complement, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE disease). Preprint. Posted online July 27, 2023. SSRN.
5. Yu CY, et al. Complement inhibitor for therapy of CHAPLE. Nat Immunol. 2021;22(2):106–108.

Approval And Revision History

February 13, 2024: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- April 1, 2024: Administrative Update: Added J Code J9376 to Medical Necessity Guideline.
- January 13, 2026: No clinical changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- February 2026: Administrative update to remove Carelink from template.

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.