

Veopoz® (pozelimab-bbfg) (Intravenous/Subcutaneous)

Effective Date: 08/01/2024

Dates Reviewed: 05/2024, 05/2025, 03/17/2026

Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

Coverage will be provided for six (6) months and may be renewed.

II. Dosing Limits

A. Max Units (per dose and over time) [HCPCS Unit]:

- Loading Dose: 3200 mg (3200 units) on day 1
- Maintenance Dose: Beginning on day 8, up to 800 mg (800 units) weekly

III. Summary of Evidence:

Veopoz (pozelimab) 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. Efficacy of Veopoz was established in a Phase 2/3, single-arm study where outcomes were compared to pre-treatment data in 10 patients with active CD55-deficient protein-losing enteropathy (PLE) who had hypoalbuminemia. Active CD55-deficient PLE was defined as hypoalbuminemia (serum albumin \leq 3.2 g/dL) with at least one clinical sign/symptom of hypoalbuminemia within the last six months. The results indicated that the median time for serum albumin to reach at least 3.5 mg/dL was 15.5 days with all 10 patients achieving normalization by Week 12 and maintaining a normal serum albumin concentration range through at least 72 weeks of treatment. The most common adverse effects of Veopoz include upper respiratory tract infections, fractures, urticaria, and alopecia.

IV. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Member is at least 1 year of age; **AND**
- The medication must be prescribed by or in consultation with a hematologist, gastroenterologist, or a specialist familiar with the treatment of rare genetic hematologic diseases; **AND**
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements; **AND**

Universal Criteria ¹

- Members must be administered a meningococcal vaccine (for serogroups A, C, W and Y, and serogroup B) at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (*If urgent Veopoz therapy is indicated in an unvaccinated member, administer meningococcal vaccine(s) as soon as possible and provide members with two weeks of antibacterial drug prophylaxis.*); **AND**

- Member must be administered vaccinations for the prevention of Streptococcus pneumoniae and Haemophilus influenzae type b (Hib) infections according to medical guidelines; **AND**
- Will not be used in combination with other complement therapies (i.e., sutimlimab, ravulizumab, avacopan, eculizumab, pegcetacoplan, etc.); **AND**
- Member does not have an unresolved Neisseria meningitidis infection; **AND**
- Member will avoid concomitant therapy with intravenous immunoglobulin, if therapy is unavoidable, the member will be monitored closely for adverse reactions and/or worsening of disease symptoms; **AND**

Complement Hyperactivation, Angiopathic thrombosis, and Protein-Losing Enteropathy Disease (CHAPLE) † Φ¹

- Member has a confirmed clinical diagnosis of CD55-deficient protein-losing enteropathy (PLE) evidenced by biallelic CD55 loss-of-function mutation detected by genotype analysis (genetic testing results must be submitted with request); **AND**
- Member has active disease as defined as hypoalbuminemia (serum albumin concentration of ≤ 3.2 g/dL) with one or more of the following signs or symptoms attributed to CD55-deficient PLE within the last six months (chart notes or medical record documentation supporting signs and symptoms of CHAPLE disease must be submitted with request):
 - abdominal pain
 - diarrhea
 - peripheral edema
 - facial edema

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

V. Renewal Criteria¹

Coverage may be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious meningococcal infections (septicemia and/or meningitis), other serious bacterial infections, serious hypersensitivity reactions, etc.; **AND** Member exhibits disease response compared to pretreatment baseline in ALL of the following with documentation provided:
 - Normalization/improvement in serum proteins (e.g., albumin, or immunoglobulin G, etc.); **AND**
 - Stabilization/improvement in signs and symptoms of disease (e.g., reduction in abdominal pain or diarrhea, reduction of peripheral or facial edema, etc.); **AND**
 - Reduction in albumin transfusion requirements, exogenous immunoglobulin, and/or hospitalization (as applicable)

VI. Dosage/Administration ¹

Indication	Dose
CHAPLE Disease	<p>Day 1 (Loading Dose): Administer a single 30 mg/kg dose by intravenous infusion.</p> <p>Day 8 and Thereafter (Maintenance Dosage): Inject 10 mg/kg as a subcutaneous injection* once weekly starting on Day 8</p> <ul style="list-style-type: none">• <i>The maintenance dosage may be increased to 12 mg/kg once weekly if there is inadequate clinical response after at least 3 weekly doses (i.e., starting Week 4).</i>• <i>The maximum maintenance dosage is 800 mg once weekly, doses greater than 400 mg require 2 injections.</i> <p><i>* Veopoz for subcutaneous use must be prepared and administered by a healthcare provider.</i></p>

VII. Billing Code/Availability Information

HCPCS Code:

- J9376 - Injection, pozelimab-bbfg, 1 mg

NDC(s):

- Veopoz 400 mg/2 mL single-dose vials for injection: 61755-0014-xx

VIII. Investigational Use

All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

IX. References

1. Veopoz [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc; December 2025. Accessed March 2026.
2. Ozen A, Chongsrisawat V, Sefer AP, et al. 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). The Lancet PrePrint article, available at SSRN: <https://ssrn.com/abstract=4485593> or <http://dx.doi.org/10.2139/ssrn.4485593>
3. Ozen A. CHAPLE syndrome uncovers the primary role of complement in a familial form of Waldmann's disease. *Immunol Rev.* 2019 Jan;287(1):20-32. doi: 10.1111/imr.12715. PMID: 30565236.
4. Ozen A, Comrie WA, Ardy RC, et al. CD55 Deficiency, Early-Onset Protein-Losing Enteropathy, and Thrombosis. *N Engl J Med.* 2017 Jul 6;377(1):52-61. doi: 10.1056/NEJMoa1615887. Epub 2017 Jun 28. PMID: 28657829; PMCID: PMC6690356.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D84.1	Defects in the complement system

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Veopoz was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Veopoz according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.