Clinical Policy: Pozelimab-bbfg (Veopoz)

Reference Number: PA.CP.PHAR.626
Effective Date: 02/2024
Last Review Date: 04/2025

Description
Pozelimab-bbfg (Veopoz™) is a complement C5 inhibitor.

FDA Approved Indication(s)
Veopoz is indicated for the treatment of adults and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Veopoz is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. CHAPLE Disease (must meet all)**:**

1. Diagnosis of CHAPLE disease confirmed by biallelic CD55 loss-of-function mutation detected by genotype analysis;
2. Prescribed by or in consultation with a gastroenterologist or physician specializing in rare genetic disorders;
3. Age ≥ 1 year;
4. Veopoz is not prescribed concurrently with other complement inhibitors (e.g. eculizumab [Soliris®, Bkemv™, Epysqli®], Ultomiris®, Piasky®);
5. Dose does not exceed both of the following (a and b):
   a. A single loading dose of 30 mg/kg intravenously on day 1;
   b. Maintenance dose, all the following (i, ii, and iii), administered subcutaneously once weekly starting on day 8 and thereafter:
      i. 800 mg;
      ii. 10 mg/kg;
      iii. If there is inadequate clinical response after at least 3 weekly doses (i.e., starting from Week 4), 12 mg/kg.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. CHAPLE Disease (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Veopoz is not prescribed concurrently with other complement inhibitors (e.g. eculizumab [Soliris®, Bkemv™, Epysqli®], Ultomiris®, Piasky®);
4. If request is for a dose increase, new dose does not exceed all the following (a, b, and c), administered subcutaneously once weekly:
   a. 800 mg;
   b. 10 mg/kg;
   c. If there is inadequate clinical response after at least 3 weekly doses (i.e., starting from Week 4), 12 mg/kg.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CHAPLE: CD55-deficient protein-losing enteropathy
FDA: Food and Drug Administration
PLE: protein-losing enteropathy

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): patients with unresolved *Neisseria meningitidis* infection
- Boxed warning(s): serious meningococcal infections

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CHAPLE disease	Single loading dose of 30 mg/kg IV on day 1, followed by 10 mg/kg SC weekly on day 8 and thereafter.	IV loading dose: 30 mg/kg SC maintenance dose: 800 mg/week

Indication	Dosing Regimen	Maximum Dose
	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 from Week 4).	

VI. Product Availability

Single-dose vial: 400 mg/2 mL

VII. References

1. Veopoz Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2024. Available at https://veopoz.com. Accessed January 22, 2025.
2. Ozen A, Chongsrisawat V, Sefer AP; Pozelimab CHAPLE Working Group. Evaluating the efficacy and safety of pozelimab in patients with CD55 deficiency with hyperactivation of complement, angiopathic thrombosis, and protein-losing enteropathy disease: an open-label phase 2 and 3 study. *Lancet*. 2024 Feb 17;403(10427):645-656. doi: 10.1016/S0140-6736(23)02358-9.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date
Policy created	01/2024
2Q 2024 annual review: added HCPCS code [J9376]; removed HCPCS codes [J3590, C9399]; references reviewed and updated.	04/2024
2Q 2025 annual review: added criterion to prevent duplicative therapy with other complement inhibitors; references reviewed and updated.	04/2025