Clinical Policy: Pozelimab-bbfg (Veopoz)

Reference Number: CP.PHAR.626
Effective Date: 08.18.23
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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:
Medicaid/HIM/ICHRA– 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. CHAPLE Disease (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
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:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of

business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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. 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).	IV loading dose: 30 mg/kg SC maintenance dose: 800 mg/week

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 February 10, 2026.

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	P&T Approval Date
Policy created pre-emptively	04.11.23	05.23
Drug is now FDA-approved – criteria updated per label; clarified maximum maintenance dose; references reviewed and updated.	08.31.23	
Added HCPCS code [J9376]; removed HCPCS codes [J3590, C9399]	02.20.24	
2Q 2024 annual review: no significant changes; references reviewed and updated.	02.22.24	05.24
2Q 2025 annual review: added criterion to prevent duplicative therapy with other complement inhibitors; references reviewed and updated.	02.18.25	05.25
2Q 2026 annual review: extended initial approval duration from 6 months to 12 months for this maintenance medication for a chronic condition; references reviewed and updated. Added ICHRA line of business.	03.31.26	05.26

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.