# Clinical Policy: Pozelimab-bbfg (Veopoz)

Reference Number: LA.PHAR.626
Effective Date: 05.06.24
Last Review Date: 07.24.234 ~~01.04.24~~
Line of Business: Medicaid

Coding Implications
Revision Log

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

****Please note: This policy is for medical benefit****

**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 Louisiana Healthcare Connections 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. 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** (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 LA.PMN.255;
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 LA.PMN.53.

**II. Continued Therapy**

**A. CHAPLE Disease** (must meet all)**:**
a. Member is currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. 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. 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 LA.PMN.255;
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 LA.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 – LA.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.<br><br>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<br>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.; August 2023. Available at https://~~www.accessdata.fda.gov/drugsatfda_docs/label/2023/761339s000lbl.pdf.~~veopoz.com. Accessed ~~August 31, 2023~~January 29, 2024.
2. Regeneron Pharmaceuticals. Open-label efficacy and safety study of pozelimab in patients with CD55-deficient protein-losing enteropathy (CHAPLE disease). ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04209634. Accessed ~~August 31, 2023~~January 29, 2024.

## Coding Implications

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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 |
|---|---|
| ~~J3590~~J9376 | ~~Unclassified biologics~~Injection, pozelimab-bbfg, 1 mg |
| ~~C9399~~ | ~~Unclassified drugs or biologicals~~ |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Converted corporate to local policy. | 01.04.24 | 05.06.24 |
| Added HCPCS code [J9376]; removed HCPCS codes [J3590, C9399]; references reviewed and updated | 07.24.24 | |

**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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.