PHARMACY POLICY STATEMENT
TRICARE

DRUG NAME	Veopoz (Pozelimab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Veopoz is a complement inhibitor that was FDA approved in August 2023 for the treatment of a CD55-deficient protein losing enteropathy, in adult and pediatric patients. Veopoz is the first FDA-approved agent for the treatment of CHAPLE disease. The study that led to its approval was an open-label, single arm study with 10 participants whose primary endpoint was met in November 2021. CHAPLE disease or complement hyperactivation angiopathic thrombosis and protein-losing enteropathy, is a rare, inherited disorder that causes an overactivity of the complement system. The complement system is a portion of the immune system that increases the ability of phagocytic cells and antibodies to combat various microbes and damaged cellular components. With this disorder, a mutation of the CD55 gene can cause the complement system to attack and disrupt its own cells. This condition can be characterized by impaired growth, edema, and severe thrombotic vascular occlusion that can be life-threatening and cause subsequent death.

Veopoz (Pozelimab) will be considered for coverage when the following criteria are met:

Complement Hyperactive, Angiopathic Thrombosis, and Protein-Losing Enteropathy (CHAPLE) Disease

For **initial** authorization:

1. Member is at least 1 year of age or older; AND
2. Medication must be prescribed by or in consultation with a geneticist, hematologist, gastroenterologist or an immunologist; AND
3. Member has a diagnosis of CHAPLE disease confirmed by **BOTH** of the following:
   a) Genotypic analysis confirming biallelic loss of function mutations to the CD55 gene;
   b) History of protein-losing enteropathy (PLE); AND
4. Member must have a baseline test confirming hypoalbuminemia; AND
5. Member must have meningococcal vaccination at least 2 weeks prior to therapy start date; AND
6. Veopoz will **NOT** be used in combination with eculizumab.
7. **Dosage allowed/Quantity limit:** Quantity limit: 16 mL per 28 days.

Loading Dose	Maintenance Dose	Maximum Maintenance Dose
Single 30 mg/kg dose	10 mg/kg dose once weekly May be increased to 12 mg/kg once weekly if inadequate response after at least 3 weekly doses	800 mg once weekly

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show an improvement of at least **ONE** of the following symptoms: daily bowel movement frequency, edema, or abdominal pain; AND
2. Normalization of serum albumin.

If all the above requirements are met, the medication will be approved for an additional 12 months.

TRICARE Prime® Demo by CareSource Military & Veterans™ considers Veopoz (Pozelimab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/06/2023	New policy for Veopoz created.

References:

1. Veopoz [package insert]. Regeneron Pharmaceuticals, Inc.; 2023.
2. Ozen A, Comrie WA, Ardy RC, et al. CD55 deficiency, early-onset protein-losing enteropathy, and thrombosis. N Engl J Med. 2017;377:52-61.
3. Regeneron Pharmaceuticals. Open-Label Efficacy and Safety Study of Pozelimab in Patients With CD55-Deficient Protein-Losing Enteropathy (CHAPLE Disease). https://clinicaltrials.gov/study/NCT04209634. Published October 2023
4. FDA approves first treatment for CD55-deficient protein-losing enteropathy (CHAPLE disease). U.S. Food and Drug Administration. https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-treatment-cd55-deficient-protein-losing-enteropathy-chaple-disease. Accessed 28 Oct 2023.
5. Biopharma Dealmakers. Methods of Diagnosing and Treating CHAPLE, A Newly Identified Orphan Disease: Collaborative Research and Licensing Opportunity. https://www.nature.com/articles/d43747-020-00626-y. Accessed October 25, 2023

Effective date: 01/01/2026
Revised date: 11/06/2023