

PHARMACY POLICY STATEMENT

Ohio Medicaid

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| 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.

CareSource 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. |
| 01/25/2024 | Approved by ODM |

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
6. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
7. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
8. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

Effective date: 04/01/2024

Revised date: 11/06/2023