Veopoz® (pozelimab-bbfg)

When requesting Veopoz® (pozelimab-bbfg), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Veopoz is indicated for the treatment of CD55-deficient protein-losing enteropathy, also known as CHAPLE (complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy) disease.

Coverage Guidelines

CHAPLE Disease

The individual must meet **all** of the following criteria for initial authorization:

- Is 1 year of age or older;
- Has had a genetic test confirming the diagnosis of CHAPLE disease with a biallelic CD55 loss-of-function pathogenic variant;
- Has a serum albumin level ≤ 3.2 g/dL;
- Has active disease and is experiencing one or more signs or symptoms within the last 6 months (e.g., abdominal pain, diarrhea, vomiting, peripheral edema, or facial edema);
- Veopoz is prescribed by a physician with expertise in managing CHAPLE disease.

The individual must meet **all** of the following criteria for reauthorization:

- Is 1 year of age or older;
- Has had a genetic test confirming the diagnosis of CHAPLE disease with a biallelic CD55 loss-of-function pathogenic variant;
- Veopoz is prescribed by a physician with expertise in managing CHAPLE disease;
- Has experienced a response to therapy.
  Note: Examples of a response to therapy include increased serum albumin levels, maintenance of serum albumin levels within a normal range, a reduction in albumin transfusions, increases in or maintenance of protein and/or immunoglobulin levels, improvement in clinical outcomes after receipt of therapy (e.g., decreases in the frequency of problematic abdominal pain, bowel movement frequency, facial edema severity, and peripheral edema severity), reduced frequency in hospitalizations, increase in growth percentiles (e.g., body weight-for age and/or stature-for-age percentiles), and/or reduced use of corticosteroids.

Approval duration (initial): 3 months
Approval duration (renewal): 12 months

Dosing Recommendations

The recommended dosage of Veopoz is as follows:

- Day 1 (loading dose): Administer a single 30 mg/kg dose by intravenous infusion after dilution.
- Day 8 and thereafter (maintenance dose): Inject 10 mg/kg as a subcutaneous injection once weekly starting on Day 8.

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).

The maximum maintenance dosage is 800 mg once weekly.

References

1. Veopoz® intravenous infusion and subcutaneous injections [prescribing information]. Tarrytown, NY: Regeneron; March 2024.
2. Ozen A, Chongsrisawat V, Sefer AP, et al, for the 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: an open-label, Phase 2 and 3 study. *Lancet*. 2024;403(10427):645-656.
3. Hoy SM. Pozelimab: first approval. *Drugs*. 2023;83(16):1551-1557.
4. Can S, Altunbas MY, Ozen A. Pharmacotherapy for CD55 deficiency with CHAPLE disease: how close are we to a cure? *Expert Opin Pharmacother*. 2024;25(11):1421-1426.