Medical Policy:
Veopoz (pozelimab-bbfg) intravenous, subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.398	October 13, 2023	October 13, 2023

Definitions

VEOPOZ is indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease. Pozelimab-bbfg is a human monoclonal immunoglobulin G4P (IgG4P) antibody directed against the terminal complement protein C5 that inhibits terminal complement activation by blocking cleavage of C5 into C5a (anaphylatoxin) and C5b, thereby blocking the formation of the membrane-attack complex (C5b-C9, a structure mediating cell lysis).

Length of Authorization

Initial: 3 months
Continuation: 12 months

Dosing Limits [Medical Benefit]

Loading dose: 30mg/kg IV on Day 1
Maintenance dose: up to 12 mg/kg subcutaneously once weekly (up to a maximum of 800 mg)

Guideline

I. Initial

1. **CD55-Deficient Protein-Losing Enteropathy (CHAPLE Disease [Complement Hyperactivation, Angiopathic thrombosis, and Protein-Losing Enteropathy]).** Approve for the duration noted below if the patient meets ONE of the following (A or B):

A. Initial Therapy. Approve for 3 months if the patient meets the following (i, ii, iii, iv, and v):
   i. Patient is ≥ 1 year of age; **AND**
   ii. Patient has had a genetic test confirming the diagnosis of CHAPLE disease with a biallelic CD55 loss-of-function mutation **[documentation required]**; **AND**
   iii. Patient meets both of the following (a and b):
      a. Patient has a serum albumin level ≤ 3.2 g/dL **[documentation required]**; **AND**
      b. According to the prescribing physician, the patient has active disease and is experiencing one or more signs or symptoms within the last 6 months; **AND**

      Note: Examples of signs and symptoms include abdominal pain, diarrhea, vomiting, peripheral edema, or facial edema.
   iv. Patient meets all of the following (a, b, and c):
      a. Patient does not have a history of meningococcal infection; **AND**
      b. Patient has received or is in compliance with updated meningococcal vaccinations according to the most current Advisory Committee on Immunization Practices recommendations; **AND**
      c. Patient has received or is in compliance with updated vaccinations for the prevention of *Streptococcus pneumonia* and *Haemophilus influenza* type b infections according to the most current Advisory Committee on Immunization Practices guidelines; **AND**
   v. Medication is prescribed by a physician with expertise in managing CHAPLE disease; **OR**

B. Patient Currently Receiving Veopoz. Approve for 1 year if the patient meets the following (i, ii, iii, and iv):
   i. Patient is ≥ 1 year of age; **AND**
   ii. Patient has had a genetic test confirming the diagnosis of CHAPLE disease with a biallelic CD55 loss-of-function mutation **[documentation required]**; **AND**
   iii. Medication is prescribed by a physician with expertise in managing CHAPLE disease; **AND**
   iv. Patient had experienced a response to therapy **[documentation required]**.

   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.

Applicable Procedure Codes

Code	Description
J3590	VEOPOZ 400MG/2ML Solution J3590 Unclassified biologics
C9399	VEOPOZ 400MG/2ML Solution C9399 Unclassified drugs or biologicals

Applicable NDCs

Code	Description
61755-0014-01	Veopoz 200mg/mL- 2mL

ICD-10 Diagnoses

Code	Description
K90.49	Malabsorption due to intolerance, not elsewhere classified
D84.1	Defects in the complement system

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	10/13/2023	New Policy

References

1. Product Information: VEOPOZ ™ intravenous, subcutaneous injection, pozelimab-bbfg intravenous, subcutaneous injection. Regeneron Pharmaceuticals Inc (per FDA), Tarrytown, NY, 2023.