

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

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 pneumoniae* and *Haemophilus influenzae* 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.