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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Biologicals	**Original Policy Date:**	September 8, 2023
Subject:	Veopoz	**Page:**	1 of 4

Last Review Date: December 13, 2024

Veopoz

Description

Veopoz (pozelimab-bbfg)

Background
Veopoz (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) (1).

Regulatory Status
FDA-approved indication: Veopoz is a complement inhibitor 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 (1).

Veopoz includes a boxed warning regarding life-threatening and fatal meningococcal infections. Complete or update meningococcal vaccination at least 2 weeks prior to administration of Veopoz unless the risks of delaying therapy outweigh the risks of developing meningococcal infection. Patients receiving Veopoz are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Veopoz is contraindicated in patients with unresolved *N. meningitidis* infection. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected (1).

Veopoz use can lead to encapsulated bacterial infections, systemic hypersensitivity reactions, and immune complex formation. Veopoz blocks terminal complement activation; therefore, patients may have increased susceptibility to encapsulated bacterial infections such as *Neisseria meningitidis, Streptococcus pneumoniae, Haemophilus influenzae,* and *Neisseria gonorrhoeae*. Interrupt treatment with Veopoz in patients with serious encapsulated bacterial infections until the infection is resolved. Hypersensitivity reactions, including anaphylaxis, have been reported with administration of complement inhibitors. Interrupt Veopoz and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur. Immune complex formation has been reported during the transition of therapy between complement inhibitors, resulting in transient decrease in drug concentrations as well as symptoms suggestive of hypersensitivity reactions. The potential for immune complex formation should be considered if switching complement inhibitors (1).

The safety and effectiveness of Veopoz in pediatric patients less than 1 year of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Veopoz may be considered **medically necessary** if the conditions indicated below are met.

Veopoz may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following:

CD55-deficient protein-losing enteropathy (PLE) (i.e., CHAPLE disease)

AND ALL of the following:

a. Patient has hypoalbuminemia
b. Meningococcal vaccination completed at least 2 weeks prior to administration of the first dose of Veopoz, unless the risks of delaying therapy outweigh the risk of developing a meningococcal infection
c. Patient will be monitored for early signs of meningococcal infections and treated immediately if infection is suspected

Prior – Approval *Renewal* Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following:

CD55-deficient protein-losing enteropathy (PLE) (i.e., CHAPLE disease)

AND ALL of the following:
a. Serum albumin has improved or stabilized
b. Patient will be monitored for early signs of meningococcal infections and treated immediately if infection is suspected

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Veopoz is indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE). Veopoz carries a boxed warning of serious meningococcal infections and is contraindicated in patients with unresolved *N. meningitidis* infection. Other serious encapsulated bacterial infections, systemic hypersensitivity reactions, and immune complex formation can occur with treatment (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Veopoz while maintaining optimal therapeutic outcomes.

References

1. Veopoz [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2024.

Policy History

Date	Action
September 2023	Addition to PA
December 2023	Annual review
March 2024	Annual review
June 2024	Annual review and reference update
September 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.