Reference number(s)
6135-A

Standard Medicare Part B Management
Veopoz

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Veopoz	pozelimab-bbfg

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

- For initial requests: chart notes, medical records and genetic test results documenting:
  - Confirmed biallelic CD55 loss-of-function mutation.
  - Hypoalbuminemia (serum albumin concentration of ≤ 3.2 g/dL).

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    - Signs and symptoms of CD-55 PLE (e.g., abdominal pain, diarrhea, peripheral edema, or facial edema).
- For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Coverage Criteria

CD55-Deficient Protein-Losing Enteropathy (PLE)[1]

Authorization of 6 months may be granted for treatment of CD55-deficient protein-losing enteropathy (PLE) when all of the following criteria are met:

- The member has a confirmed biallelic CD55 loss-of-function mutation detected by genotype analysis.
- The member has hypoalbuminemia (serum albumin concentration of ≤ 3.2 g/dL).
- The member has one or more of the following signs and symptoms of CD-55 PLE within the past 6 months:
    - Abdominal pain
    - Diarrhea
    - Peripheral edema
    - Facial edema

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy (e.g., normalization of serum albumin, improvement in signs and symptoms of disease, and/or decrease in number of hospitalizations and infections).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Veopoz.

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- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Veopoz are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

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

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