Reference number(s)
6684-A

Standard Medicare Part B Management Vafseo

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
Vafseo	vadadustat

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 Indication

Vafseo is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

Limitations of Use

- Vafseo has not been shown to improve quality of life, fatigue, or patient well-being.
- Vafseo is not indicated for use:
    - As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
    - In patients with anemia due to chronic kidney disease not on dialysis.

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.

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Reference number(s)
6146-A

Coverage Criteria

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion.

Anemia due to Chronic Kidney Disease (CKD)

Authorization of 12 weeks may be granted for the treatment of anemia due to chronic kidney disease in adult members receiving dialysis for at least 3 months with a pretreatment hemoglobin of less than or equal to 11 grams per deciliter (g/dL).

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 weeks may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Vafseo.
- Vafseo is being used to treat anemia due to chronic kidney disease (CKD) in adult members receiving dialysis.
- Vafseo has been effective for treating the diagnosis or condition.

Summary of Evidence

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

- The prescribing information for Vafseo.
- 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 Vafseo are covered.

Explanation of Rationale

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Support for FDA-approved indications (anemia due to chronic kidney disease) can be found in the manufacturer's prescribing information.

References

1. Vafseo [package insert]. Cambridge, MA: Akebia Therapeutics, Inc.; March 2024.

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