Reference number(s)
6459-A

Specialty Guideline 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.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Note: Requirements regarding pre-treatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are

receiving iron therapy before starting Vafseo. Members may not use Vafseo concomitantly with erythropoiesis-stimulating agents.

Anemia Due to Chronic Kidney Disease (CKD)

Authorization of 12 weeks may be granted for treatment of anemia due to chronic kidney disease in adult members when both of the following criteria are met:

- The member has been receiving dialysis for at least three months.
- The pretreatment hemoglobin level is less than or equal to 11 grams per deciliter (g/dL).

Continuation of Therapy

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before continuation of treatment with Vafseo. Members may not use Vafseo concomitantly with erythropoiesis-stimulating agents.

All members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of Vafseo treatment must show a response with a rise in hemoglobin of greater than or equal to 1 g/dL. Members who have completed less than 12 weeks of Vafseo treatment and have not yet responded with a rise in hemoglobin of greater than or equal to 1 g/dL may be granted authorization for up to 12 weeks to allow for sufficient time to demonstrate a response.

Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in adult members receiving dialysis with current hemoglobin less than 12 g/dL.

Reference

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