Applicable Drugs: Vafseo (vadadustat)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/24/2025

Date Last Reviewed / Revised: 10/16/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

I. Diagnosis of anemia due to chronic kidney disease (CKD) and the following criteria A through F are met:
   A. Documentation that the patient has received dialysis for ≥ 3 months
   B. Prescriber attestation that other causes of anemia have been ruled out or corrected when possible (eg, iron deficiency, inflammatory conditions, blood loss, hemolysis)
   C. Documented current hemoglobin level <10 g/dL (within the last 30 days)
   D. Documentation of adequate iron stores that meet the following criteria i and ii:
      i. Transferrin saturation (TSAT) ≥ 20% (within the last 30 days)
      ii. Ferritin ≥ 100 mcg/L (within the last 30 days)
   E. Documentation that the patient is hyporesponsive to one erythropoiesis stimulating agent (ESA) when criteria i and ii are met:
      i. Patient completed a 2-month trial of an erythropoiesis stimulating agent
      ii. Patient failed to reach the target hemoglobin level and criteria 1 or 2 is met:
         1. Required >300 IU/kg/week of SQ epoetin or > 450 IU/kg/week IV epoetin
         2. Required at least 1.5 mcg/kg/week of darbepoetin alfa
   F. Documentation of baseline serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST), and total bilirubin

II. Documentation that Vafseo (vadadustat) will not be used in combination with an erythropoiesis-stimulating agent (ESA)

III. Minimum age requirement: 18 years old.

IV. Treatment must be prescribed by or in consultation with a hematologist or nephrologist.

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- Use as a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia
- Treatment of anemia in non–dialysis-dependent chronic kidney disease
- Active malignancy
- Myocardial infarction, cerebrovascular event, or acute coronary syndrome within the last 3 months
- Concurrent use with an erythropoiesis-stimulating agent (ESA)

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Maximum dose: 600mg daily.
    - 150mg tablets, up to 30 tablets per 30 days
    - 300mg tablets, up to 60 tablets per 30 days
    - 450mg tablets, up to 30 tablets per 30 days

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes documenting treatment response including, but not limited to:
    1) Increase or stabilization in hemoglobin levels
    2) Reduction or absence of red blood cell transfusions
    3) Current hemoglobin ≤ 11 g/dL
    4) Current serum ferritin level ≥ 100 mcg/L and serum transferrin saturation ≥ 20%

Appendix

N/A

References

1. Vafseo. Prescribing information. Akebia Therapeutics, Inc; 2026. Accessed October 1, 1026. https://www.vafseohcp.com/pdf/prescribing-information.pdf

2. Kidney Disease: Improving Global Outcomes (KDIGO) anemia work group. KDIGO 2026 clinical practice guideline for the management of anemia in chronic kidney disease (CKD). *Kidney Int.* 2026;109(1S):S1-S99. doi:10.1016/j.kint.2025.06.006
3. Bhandari S, Spencer S, Oliveira B, et al. UK kidney association clinical practice guideline: update of anaemia of chronic kidney disease. *BMC Nephrol.* 2025;26(1):193. Published 2025 Apr 16. doi:10.1186/s12882-025-04115-1

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.