CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Vafseo (vadadustat)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Vafseo, approved by the FDA in 2024, is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months. It has not been shown to improve quality of life, fatigue, or patient well-being, and is not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia, or for patients not on dialysis.
Erythropoiesis-stimulating agents (ESAs) are the standard of care for treating anemia in CKD (especially in dialysis patients). Vafseo is the second approved HIF inhibitor, following Jesduvroq (daprodustat). In the Phase 3 INNO2VATE trials, Vafseo was noninferior to darbepoetin alfa in efficacy (hemoglobin correction) and cardiovascular (CV) safety outcomes. It has a boxed warning for increased risk of thrombotic vascular events. The lowest dose sufficient to reduce the need for red blood cell transfusions should be used.

Vafseo (vadadustat) will be considered for coverage when the following criteria are met:

Anemia of Chronic Kidney Disease (CKD)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has a diagnosis of anemia due to CKD; AND
4. Member has been receiving dialysis for at least 3 months; AND
5. Member's labs show hemoglobin level less than 10 g/dL in the last 30 days; AND
6. Member's labs show adequate iron stores with both of the following:
   a) Transferrin saturation (TSAT) is at least 20%
   b) Ferritin is at least 100 mcg/L; AND
7. Member has tried and failed an erythropoiesis stimulating agent (ESA) for at least 4 weeks; AND
8. Member does NOT have uncontrolled hypertension.
9. **Dosage allowed/Quantity limit:** Start 300 mg orally once daily. Adjust based on hemoglobin levels per prescribing information; do not target hemoglobin >11 g/dL. Max dose 600 mg once daily. (QL: 60 tablets per 30 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show increased hemoglobin compared to baseline; AND
2. Current hemoglobin level does not exceed 11 g/dL.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Vafseo (vadadustat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/12/2024	New policy for Vafseo created.
04/01/2025	Annual review; no changes.

References:

1. Vafseo [prescribing information]. Akebia Therapeutics, Inc.; 2024.
2. Eckardt KU, Agarwal R, Aswad A, et al. Safety and Efficacy of Vadadustat for Anemia in Patients Undergoing Dialysis. *N Engl J Med*. 2021;384(17):1601-1612. doi:10.1056/NEJMoa2025956
3. Kliger AS, Foley RN, Goldfarb DS, et al. KDOQI US commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. *Am J Kidney Dis*. 2013;62(5):849-859. doi:10.1053/j.ajkd.2013.06.008
4. Natale P, Palmer SC, Jaure A, et al. Hypoxia-inducible factor stabilisers for the anaemia of chronic kidney disease. *Cochrane Database Syst Rev*. 2022;8(8):CD013751. Published 2022 Aug 25. doi:10.1002/14651858.CD013751.pub2

Effective date: 10/01/2025
Revised date: 04/01/2025