BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.85.059

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	October 18, 2024
Subject:	Vafseo	**Page:**	1 of 4

Last Review Date: December 13, 2024

Vafseo

Description

Vafseo (vadadustat)

Background
Vafseo (vadadustat) is a reversible inhibitor of hypoxia-inducible factor prolyl hydroxlase 1 (HIF PH1), HIF PH2, and HIF PH3. This activity results in the stabilization and nuclear accumulation of HIF-1α and HIF-2α transcription factors, and increased production of erythropoietin (1).

Regulatory Status
FDA-approved indication: Vafseo 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 (1).

Limitations of Use: (1)
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 transfusion in patients requiring immediate correction of anemia
- In patients with anemia due to CKD not on dialysis

Vafseo has a boxed warning of increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access. Vafseo increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE). A target hemoglobin level greater than 11 g/dL is expected to increase the risk of death and arterial and venous thrombotic events. Use the lowest dose of Vafseo sufficient to reduce the need for red blood cell transfusions (1).

Vafseo is contraindicated in patients with uncontrolled hypertension (1).

Vafseo has been associated with hepatotoxicity, worsening hypertension, seizures, gastrointestinal erosion, and malignancy. ALT, AST, and bilirubin should be measured prior to initiation, monthly after initiation for the first 6 months, and as clinically indicated. Blood pressure should be monitored, and anti-hypertensive therapy should be adjusted as needed. Patients should be monitored for new-onset seizures, premonitory symptoms, or change in seizure frequency. Gastrointestinal erosion has been reported in patients receiving Vafseo. Risk should be considered in patients at increased risk for gastrointestinal erosions. Vafseo may have unfavorable effects on cancer growth. Therefore, the use of this medication is not recommended if the patient has active malignancy (1).

The safety and effectiveness of Vafseo pediatric patients less than 18 years of age have not been established (1).

Related policies
Jesduvroq

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vafseo may be considered **medically necessary** if the conditions indicated below are met.

Vafseo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic kidney disease

AND ALL of the following:

a. Patient has been on dialysis for at least three months prior to treatment
b. Patient is currently on dialysis
c. Hemoglobin ≤11 g/dL
d. Serum ferritin ≥ 100 ng/ml (labs must have been taken within the last 3 months)
e. Patient requires red blood cell (RBC) transfusions to manage anemia
f. Patient has had an inadequate treatment response, intolerance, or contraindication to an erythropoiesis stimulating agent (e.g., darbepoetin alfa, epoetin alfa)
g. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Vafseo therapy is appropriate

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic kidney disease

AND ALL of the following:

a. Patient is currently on dialysis
b. Hemoglobin ≤11 g/dL
c. Serum ferritin ≥ 100 ng/ml (labs must have been taken within the last 3 months)
d. The need for red blood cell (RBC) transfusions has reduced since initiating therapy
e. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Vafseo therapy is appropriate

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Vafseo is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to CKD in patients who have been receiving dialysis for at least three months. Vafseo is not indicated for the treatment of anemia of CKD in patients who are not dialysis dependent. Vafseo has a box warning regarding an increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access. Treatment can cause hepatotoxicity, worsening hypertension, seizures, and gastrointestinal erosion. Vafseo is not recommended if the patient has active malignancy due to unfavorable effects on cancer growth. The safety and effectiveness of Vafseo in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Vafseo while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Action
October 2024	Addition to PA
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.