Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCHEM038.1225	**HEMATOLOGICAL AGENT** **VAFSEO®** (vadadustat tablet)
Effective Date: 2/1/2026	**Review/Revised Date**: 10/24, 11/24, 11/25 (KN)
Original Effective Date: 06/24	**P&T Committee Meeting Date**: 04/24, 10/24, 12/24, 12/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA)-Approved Indications

REQUIRED MEDICAL INFORMATION:
For initial authorization, all the following must be met:
1. Documentation of anemia due to chronic kidney disease (CKD)
2. Documentation that the patient has received dialysis for at least three months
3. Adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%
4. Documentation that the patient is hyporesponsive to erythropoiesis-stimulating agent therapy

For reauthorization, all the following must be met:
1. Documentation of anemia due to CKD
2. Documentation the patient has experienced a therapeutic response, defined by an increase in hemoglobin from baseline

EXCLUSION CRITERIA:
1. Uncontrolled hypertension
2. Combination with erythropoiesis-stimulating therapy

AGE RESTRICTIONS:
May be approved for patients aged 18 years and older

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a nephrologist, or hematologist.

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved for one year.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Vadadustat is a hypoxia-inducible factor prolyl hydroxylase (HIP-PH) inhibitor approved for the treatment of anemia due to chronic kidney disease (CKD).

FDA APPROVED INDICATIONS:
Vadadustat (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: Vadadustat has not been shown to improve quality of life, fatigue, or patient well-being; vadadustat is not indicated for use as a substitute for red blood cell transfusions in patients who require immediate correction of anemia, or in patients with anemia due to CKD not on dialysis.

POSITION STATEMENT:
Vadadustat
Vadadustat's efficacy is established in two phase 3, active-controlled, non-inferiority trials that vadadustat improves and maintains hemoglobin levels in adults with CKD on dialysis; results from both trials showed that vadadustat was non-inferior to darbepoetin alfa.

Vadadustat is the second oral HIF-PH inhibitor approved for the treatment of anemia due to CKD in adult patients on dialysis; in February 2023 daprodustat was approved for the same indication in adults who have been receiving dialysis for at least four months.

Safety for vadadustat includes:

- Boxed warnings include increased risk of death, myocardial infarction, stroke, venous thromboembolism and thrombosis of vascular access
- Contraindications include uncontrolled hypertension. Vadadustat does not carry the same increased risk of hospitalization for heart failure as the other HIF-PH inhibitor, daprodustat
- Other warnings and precautions include hepatotoxicity, hypertension, seizures, gastrointestinal erosion, malignancy, adverse reactions in patients not on dialysis
- Common adverse reactions occurring in greater than 5% of patients include hypertension, diarrhea, headache, nausea, fatigue, abdominal pain, vomiting, gastrointestinal erosion, dizziness, dyspnea, arteriovenous fistula thrombosis, dialysis related complication

Vadadustat is unique compared to ESA therapy as it is administered by mouth in a tablet formulation while ESA therapy are injections. Additionally, it is administered daily while ESA therapy is commonly administered on a weekly basis (such as three times a week, once a week, or once every couple of weeks).

The Kidney Disease Improving Global Outcomes (KDIGO) 2025 draft guidelines recommend that all correctable causes of anemia, such as iron-deficiency, should be addressed prior to starting therapy with an ESA or HIF-PH. The guidelines recommend utilizing an ESA as first-line therapy rather than a HIF-PH due to the well-documented benefits and risks associated with ESAs. They also recommend avoiding concomitant therapy with both an ESA and a HIF-PH.

BILLING GUIDELINES AND CODING:

CODES*		
HCPCS	J0901	Vadadustat, oral, 1 mg (for esrd on dialysis)

*Coding Notes:

• The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.

• HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCE/RESOURCES:

1. Vadadustat (Vafseo®) Package insert. Cambridge, MA: Akebia Therapeutics, Inc; June 2024.
2. Vadadustat In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically. Accessed November 5, 2025.
3. Vadadustat In: Lexi-Drugs Online [Internet database]. Hudson, OH: Lexi-Comp, Inc. Updated periodically. Accessed November 8, 2024.
4. Eckardt KU, et al. Global Phase 3 programme of vadadustat for treatment of anaemia of chronic kidney disease: rationale, study design and baseline characteristics of dialysis dependent patients in the INNO2VATE trials. Nephrol Dial Transplant. 2021;36(11):2039– 2048.
5. Eckardt KU, et al. Safety and efficacy of vadadustat for anemia in patients undergoing dialysis. N Engl J Med. 2021;384(17):1601–1612.
6. KDIGO 2025 Clinical Practice Guideline for Anemia in Chronic Kidney Disease. November 2024 Draft. https://kdigo.org/wp-content/uploads/2024/11/KDIGO-2025-Anemia-in-CKD-Guideline_Public-Review-Draft_Nov42024.pdf. Accessed November 5, 2025.