Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 01/01/2025**
Policy Number: PA.CP.PHAR.677	**Effective Date: 01/2025** **Revision Date: 12/2024**
Policy Name: Vadadustat (Vafseo)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Craig A. Butler, MD MBA**	**Signature of Authorized Individual:**

Clinical Policy: Vadadustat (Vafseo)

Reference Number: PA.CP.PHAR.677
Effective Date: 01/2025
Last Review Date: 12/2024

Description
Vadadustat (Vafseo®) is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor.

FDA Approved Indication(s)
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.

Limitation(s) of use:
- Not shown to improve quality of life, fatigue, or patient well-being.
- Not indicated for use:
  - As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
  - In patients with anemia due to CKD not on dialysis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Vafseo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. **Anemia due to Chronic Kidney Disease** (must meet all)**:**
   1. Diagnosis of anemia of CKD;
   2. Age ≥ 18 years;
   3. Prescribed by or in consultation with a hematologist or nephrologist;
   4. Member has received dialysis for ≥ 3 months;
   5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
   6. Pretreatment hemoglobin level of 8 to 11 g/dL;
   7. Trial and failure of Retacrit® or Epogen®, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for Retacrit and Epogen.*

   Approval duration: 6 months

2. **Other diagnoses/indications**
   1. Trial and failure of Retacrit® or Epogen®, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for Retacrit and Epogen*
   2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Anemia due to Chronic Kidney Disease (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Current hemoglobin ≤ 11 g/dL;
4. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
2. Trial and failure of Retacrit® or Epogen®, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Retacrit and Epogen*
   Approval duration: Duration of request or 12 months (whichever is less); or
3. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
ESA: erythropoiesis-stimulating agent
FDA: Food and Drug Administration
HIF PH: hypoxia-inducible factor prolyl hydroxylase

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Retacrit (epoetin alfa-epbx), Epogen (epoetin alfa)	**Anemia due to CKD** Initial dose: 50 to 100 Units/kg 3 times weekly (adults) IV or SC and 50 Units/kg 3 times weekly (pediatric patients ages 1 month or older) IV or SC. Individualize maintenance dose. IV route recommended for patients on hemodialysis	Varies depending on indication, frequency of administration, and individual response

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
†Off-label indication

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to Vafseo or any of its components, uncontrolled hypertension
- Boxed warning(s): increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Anemia due to CKD	Recommended starting dose: 300 mg PO QD Adjust dose in increments of 150 mg up to a maximum of 600 mg to achieve or maintain Hb levels within 10 g/dL to 11 g/dL. Increase the dose no more frequently than once every 4 weeks. If switching from an erythropoiesis-stimulating agent (ESA) and ESA rescue treatment is needed, Vafseo should be paused and may be resumed when Hb levels are ≥ 10 g/dL. Depending on the ESA used for rescue, the pause in Vafseo treatment should be extended to: • 2 days after last dose of epoetin • 7 days after last dose of darbepoetin alfa • 14 days after last dose of methoxy polyethylene glycol-epoetin beta Following ESA rescue, Vafseo should be resumed at the prior dose or with a dose that is 150 mg greater than the prior dose.	600 mg/day

VI. Product Availability

Tablets: 150 mg, 300 mg, 450 mg

VII. References

1. Vafseo Prescribing Information. Cambridge, MA: Akebia Therapeutics; March 2024. Available at https://www.vafseo.com. Accessed April 8, 2024.
2. Clinical Pharmacology [database online]. Elsevier, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed April 8, 2024.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 8, 2024.
4. Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Official Journal of the International Society of Nephrology – Kidney International Supplements August 2012. 2(4): 279-335.
5. Sarnak MJ, Agarwal R, Boudville N, et al. Vadadustat for treatment of anemia in patients with dialysis-dependent chronic kidney disease receiving peritoneal dialysis. Nephrol Dial Transplant. 2023 Sep 29; 38(10): 2358-2367.

6. Eckardt KU, Agarwal R, Aswad A, et al. Safety and efficacy of vadadustat for anemia in patients undergoing dialysis. N Engl J Med. 2021 Apr 29; 384(17): 1601-1612.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0901	Vadadustat, oral, 1 mg (for esrd on dialysis)

Reviews, Revisions, and Approvals	Date
Policy created	12/2024