# Clinical Policy: Vadadustat (Vafseo)

Reference Number: LA.PHAR.677
Effective Date: 08.29.24
Last Review Date: ~~05.24.24~~01.07.25
Line of Business: Medicaid

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

****Please note: This policy is for medical benefit****

**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 Louisiana Healthcare Connections that Vafseo is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. 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. Member meets one of the following (a or b):
   a. Failure of Retacrit®, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Retacrit*



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b. If Retacrit is unavailable due to shortage, failure of Epogen®, unless contraindicated or clinically significant adverse effects are experienced.
**Prior authorization may be required for Epogen*

**Approval duration:** 6 months

**B. Other diagnoses/indications** (must meet all)**:**
1. Member meets one of the following (a or b):
   a. One of the following (i or ii):
      i. Failure of Retacrit, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for Retacrit*
      ii. If Retacrit is unavailable due to shortage, failure of Epogen, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for Epogen*
   b. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (see *Appendix D*);
2. Member meets one of the following (a or b):
   a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
   b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2a above does not apply, refer to the off-label use policy LA.PMN.53

**II. Continued Therapy**

**A. Anemia due to Chronic Kidney Disease** (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. 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

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**B. Other diagnoses/indications** (must meet all)**:**
1. Member meets one of the following (a or b):
   a. One of the following (i or ii):
      i. Failure of Retacrit, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for Retacrit*
      ii. If Retacrit is unavailable due to shortage, failure of Epogen, unless contraindicated or clinically significant adverse effects are experienced;
      **Prior authorization may be required for Epogen*
   b. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (see *Appendix D*);
2. Member meets one of the following (a or b):

a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer LA.PMN.255
b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2a above does not apply, refer to the off-label use policy for LA.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 – refer to LA.PMN.53, or evidence of coverage documents.

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**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**<br>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

~~*Appendix D: States with Regulations against Redirections in Certain Oncology Settings*~~

| ~~State~~ | ~~Step Therapy Prohibited?~~ | ~~Notes~~ |
|---|---|---|
| ~~LA~~ | ~~Yes~~ | ~~For stage 4 advanced, metastatic cancer or associated conditions. Exception if "clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.~~ |

**V. Dosage and Administration**

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Anemia due to CKD | Recommended starting dose: 300 mg PO QD<br>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.<br><br>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:<br>• 2 days after last dose of epoetin<br>• 7 days after last dose of darbepoetin alfa<br>• 14 days after last dose of methoxy polyethylene glycol-epoetin beta<br>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 |
|---|---|
| ~~C9399~~ J0901 | ~~Unclassified drugs or biologicals~~Vadadustat, oral, 1 mg (for esrd on dialysis) |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Converted to Local Policy | 05.21.24 | 07.29.24 |
| Removal of Appendix D as LDH confirmed it is not applicable to Medicaid. HCPCS code added [J0901] and removed code [C9399]. | 01.07.25 | |

**Important Reminder**
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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