

**Clinical Policy: Vadadustat (Vafseo)**

Reference Number: CP.PHAR.677

Effective Date: 06.01.24

Last Review Date: 05.25

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**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 health plans affiliated with Centene Corporation® 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  $\geq$  18 years;
3. Prescribed by or in consultation with a hematologist or nephrologist;
4. Member has received dialysis for  $\geq$  3 months;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level  $\geq$  100 mcg/L or serum transferrin saturation  $\geq$  20%;
6. Pretreatment hemoglobin level of 8 to 11 g/dL;
7. Member meets both of the following (a and b):\*

*\*For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395.*

- a. Failure of Retacrit®, unless contraindicated, clinically significant adverse effects are experienced, or Retacrit is unavailable due to shortage;  
*\*Prior authorization may be required for Retacrit*
- b. If member is unable to use Retacrit, failure of Epogen®, unless contraindicated or clinically significant adverse effects are experienced.

*\*Prior authorization may be required for Epogen*

8. Vafseo is not prescribed concurrently with Jesduvroq™;

**Approval duration:**

**Medicaid/HIM** – 6 months

**Commercial** – 6 months or to member's renewal period, whichever is longer

**B. Other diagnoses/indications (must meet all):**

1. Member meets one of the following (a or b):

a. Both of the following (i and ii):\*

*\*For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395.*

i. Failure of Retacrit, unless contraindicated, clinically significant adverse effects are experienced, or Retacrit is unavailable due to shortage;

*\*Prior authorization may be required for Retacrit*

ii. If member is unable to use Retacrit, 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 one of the following policies (i or ii):

i. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

ii. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

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 the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Member meets one of the following (a or b):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);

2. Member is responding positively to therapy;

3. Current hemoglobin  $\leq$  11 g/dL;

4. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level  $\geq 100$  mcg/L or serum transferrin saturation  $\geq 20\%$ .
5. Vafseo is not prescribed concurrently with Jesduvroq;

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to member's renewal period, whichever is longer

**B. Other diagnoses/indications (must meet all):**

1. Member meets one of the following (a or b):\*

*\*For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395.*

- a. Both of the following (i and ii):

- i. Failure of Retacrit, unless contraindicated, clinically significant adverse effects are experienced, or Retacrit is unavailable due to shortage;

*\*Prior authorization may be required for Retacrit*

- ii. If member is unable to use Retacrit, 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 one of the following policies (i or ii):

- i. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

- ii. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

- 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 the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

**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)	<b>Anemia due to CKD</b> 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<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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
FL	Yes	For stage 4 metastatic cancer and associated conditions.
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.
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.
MS	Yes	<i>*Applies to HIM requests only*</i> For advanced metastatic cancer and associated conditions
NV	Yes	Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
OH	Yes	<i>*Applies to Commercial and HIM requests only*</i> For stage 4 metastatic cancer and associated conditions
OK	Yes	<i>*Applies to HIM requests only*</i> For advanced metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer

State	Step Therapy Prohibited?	Notes
TN	Yes	For advanced metastatic cancer and associated conditions
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

## V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Anemia due to CKD	<p>Recommended starting dose: 300 mg PO QD</p> <p>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.</p> <p>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 <math>\geq 10</math> g/dL. Depending on the ESA used for rescue, the pause in Vafseo treatment should be extended to:</p> <ul style="list-style-type: none"> <li>• 2 days after last dose of epoetin</li> <li>• 7 days after last dose of darbepoetin alfa</li> <li>• 14 days after last dose of methoxy polyethylene glycol-epoetin beta</li> </ul> <p>Following ESA rescue, Vafseo should be resumed at the prior dose or with a dose that is 150 mg greater than the prior dose.</p>	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 January 17, 2025.
2. Clinical Pharmacology [database online]. Elsevier, Inc.; 2024. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed February 25, 2025.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 25, 2025.
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.

<b>HCPCS Codes</b>	<b>Description</b>
J0901	Vadadustat, oral, 1 mg (for esrd on dialysis)

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>P&amp;T Approval Date</b>
Policy created.	04.08.24	05.24
Updated Appendix E to include Mississippi.	06.06.24	
HCPCS code added [J0901] and removed code [C9399].	11.07.24	
2Q 2025 annual review: added requirement that Vafseo is not prescribed concurrently with Jesduvroq; extended continuation of therapy approval duration from 6 to 12 months for Medicaid/HIM; references reviewed and updated. Per March SDC, modified to require redirection to both Retacrit and Epogen (if member is unable to use Retacrit). Added step therapy bypass for IL HIM per IL HB 5395.	03.11.25	05.25

### **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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

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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.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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