

Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitors
Vafseo (vadadustat)
Effective 04/03/2025

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Vafseo (vadadustat) 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.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of dialysis dependent anemia of chronic kidney disease
2. Member is ≥ 18 years of age
3. Prescriber is a nephrologist or consult notes from a nephrologist are provided
4. Member has been receiving hemodialysis or peritoneal dialysis for \geq three months
5. Inadequate response (defined as hyporesponsiveness*) or adverse reaction to ONE or contraindication to ALL of the following:
 - a. Aranesp
 - b. Epogen or Procrit
 - c. Mircera
 - d. Retacrit
6. Appropriate dosing

*Hyporesponsiveness to treatment is defined by the need for any of the following:

- 300 units/kg per week of subcutaneous epoetin alfa
- > 450 units/kg per week of intravenous epoetin alfa
- > 1.5 mcg/kg per week of darbepoetin alfa

- no increase in hemoglobin (Hb) concentration from baseline after the first month of ESA treatment with appropriate weight-based dosing
- two ESA dose increases up to 50% beyond the dose previously stabilized on to maintain a stable Hb concentration
- an ESA dose increase beyond double the initial weight-based dose or previous stable dose

Continuation of Therapy

Resubmission by prescriber must document positive response to therapy.

Limitations

1. Approvals will be granted for 6 months.

References

1. Vafseo® [package insert]. Cambridge (MA): Akebia, Inc.; 2024 Mar.
2. Eckardt KU, Agarwal R, Aswad A, Awad A, Block GA, Bacci MR, et al. Safety and Efficacy of Vadadustat for Anemia in Patients Undergoing Dialysis. *N Engl J Med*. 2021 Apr 29;384(17):1601-1612.
3. FDA Approves First Oral Treatment for Anemia Caused by Chronic Kidney Disease for Adults on Dialysis [press release on the Internet]. Rockville (MD): Food and Drug Administration (US); 2023 Feb 01 [cited 2023 Dec 19]. Available from: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-treatment-anemia-caused-chronic-kidney-disease-adults-dialysis>
4. Berns JS, Qunibi WY. Treatment of anemia in patients on dialysis. In: Schwab SJ, Curhan GC (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2024 [cited 2024 Nov 07]. Available from: <http://www.utdol.com/utd/index.do>
5. Kidney Disease: Improving Global Outcomes (KDIGO). Clinical Practice Guideline for Anemia in Chronic Kidney Disease (CKD): Public Review Draft, 2025 [guideline on the Internet]. Brussels, Belgium: KDIGO; 2024 Nov [cited 2024 Nov 22]. Available from: <https://kdigo.org/wp-content/uploads/2024/11/KDIGO-2025-Anemia-in-CKD-Guideline-Public-Review-Draft-Nov42024.pdf>.
6. Brunton S, Fishbane S, Goldman JD, Wright E. Anemia in CKD in Primary Care: Executive Summary. *Clin Diabetes*. 2022;41(1):81-84

Review History

03/12/25 – Created for P&T. Adopted MH criteria. New drug added and will be managed via medical benefit.
Effective 4/3/25

