Mass General Brigham
Health Plan

Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitors
Vafseo (vadadustat)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Vafseo (vadadustat) is a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) 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
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of 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. History of hemodialysis or peritoneal dialysis for ≥ 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 4/4/25

11/4/26 – Reviewed and updated for P&T. Updated formatting. Effective 1/4/27