

Vadadustat (VAFSEO)

Criteria for Use

AUG 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If any of the following are selected, the patient will NOT meet criteria for vadadustat (VAFSEO).

- Uncontrolled Hypertension
- History of myocardial infarction, cerebrovascular event or acute coronary syndrome in prior 3 months
- Cirrhosis or active, acute liver disease
- Unmanageable drug-drug interaction
- Patient risk of gastrointestinal erosion (i.e. history of GI bleed, peptic ulcer disease, current tobacco and alcohol use) outweighs potential benefit of vadadustat

Inclusion Criteria

All of the following criteria must be met.

- The patient has anemia related to chronic kidney disease and is receiving dialysis chronically (>3 months)
 - The patient has had an insufficient response to or is unable to use ESA's
 - Care is being provided by a VHA dialysis provider ^1
- ^{^1} For patients receiving dialysis service via contracted care (i.e. Community Care), vadadustat is a component of the contracted care bundled payment and if prescribed is to be supplied by the contracted care provider.

Additional Inclusion Criteria

- For females who can become pregnant: Pregnancy should be excluded prior to receiving vadadustat
- For females who can become pregnant counseling has been provided on potential risks vs benefits of treatment and the use of effective contraception during therapy

Other Justification
