AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitors (Medical)

Drug Requested: select one below

❑ **Jesduvroq** (daprodustat) **J0889**	❑ **Vafseo** (vadadustat) **J8499**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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Recommended Dosage:

- **Jesduvroq:**

Strength	Maximum number of tablets per day	# Billable units per day	# Billable units per 30 days
1 mg	1 Jesduvroq tablet per day	1 billable unit	30 billable units
2 mg	1 Jesduvroq tablet per day	2 billable units	60 billable units
4 mg	1 Jesduvroq tablet per day	4 billable units	120 billable units
6 mg	2 Jesduvroq tablets per day	12 billable units	360 billable units
8 mg	3 Jesduvroq tablets per day	24 billable units	720 billable units

- **Vafseo:** 300 mg daily. Adjust daily dose in increments of 150 mg (range: 150 mg/day to maximum dose of 600 mg/day)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Medication is prescribed by or in consultation with a nephrologist
- ❑ Member has a diagnosis of anemia due to chronic kidney disease (CKD) and has been receiving dialysis for at least 4 months for Jesduvroq (daprodustat) or 3 months for Vafseo (vadadustat)
- ❑ Provider attests other causes of anemia have been ruled out (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding)
- ❑ Member's hemoglobin level is less than 10 g/dL **(must submit lab test results from within the last 30 days)**
- ❑ Member's labs show adequate iron stores with **BOTH** of the following **(must submit lab test results from within the last 30 days)**:
  - ❑ Transferrin saturation is at least 20%
  - ❑ Ferritin is at least 100 mcg/L
- ❑ Member has tried and failed an erythropoiesis stimulating agent (ESA) for at least 4 weeks **(must submit chart notes and/or lab test results documenting therapy failure)**
- ❑ Member will **NOT** be using the requested medication in combination with an ESA (e.g., Aranesp®, Epogen®, Mircera®, Procrit®, Retacrit®) or other hypoxia-inducible factor prolyl hydroxylase inhibitor medications (e.g., Jesduvroq, Vafseo)

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- ❑ Member does **NOT** have uncontrolled hypertension
- ❑ Member does **NOT** have severe hepatic impairment (Child-Pugh Class C)
- ❑ Member does **NOT** have active malignancy
- ❑ Member has **NOT** experienced a myocardial infarction, cerebrovascular event, or acute coronary syndrome within the last 3 months
- ❑ Member is **NOT** taking a strong cytochrome P450 (CYP) 2C8 inhibitor (e.g., gemfibrozil)

Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member's hemoglobin has increased compared to baseline **(must submit lab test results from within the last 30 days)**
- ❑ Member's current hemoglobin level does **NOT** exceed 12 g/dL
- ❑ Member's labs show adequate iron stores with **BOTH** of the following **(must submit lab test results from within the last 30 days)**:
  - ❑ Transferrin saturation is at least 20%
  - ❑ Ferritin is at least 100 mcg/L
- ❑ Member will **NOT** be using the requested medication in combination with an ESA (e.g., Aranesp®, Epogen®, Mircera®, Procrit®, Retacrit®) or other hypoxia-inducible factor prolyl hydroxylase inhibitor medications (e.g., Jesduvroq, Vafseo)

Medication being provided by Specialty Pharmacy – Proprium Rx

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee**: ~~11/16/2023;~~ **9/26/2024**
REVISED/UPDATED/REFORMATTED: ~~11/8/2023; 12/11/2023; 2/06/2024;~~ **10/15/2024**