Clinical Policy: Daprodustat (Jesduvroq)

Reference Number: PA.CP.PHAR.628
Effective Date: 08/2023
Last Review Date: 07/2023

Description
Daprodustat (Jesduvroq™) is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor.

FDA Approved Indication(s)
Jesduvroq is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four 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 transfusion in patients requiring immediate correction of anemia.
  - In patients 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 PA Health & Wellness® that Jesduvroq 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 ≥ 18 years;
3. Prescribed by or in consultation with a hematologist or nephrologist;
4. Member has received dialysis for ≥ 4 months;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
6. Pretreatment hemoglobin level of 8 to 11.5 g/dL;
7. Member has failed unless contraindicated or clinically significant adverse effects are experienced to Retacrit® and Epogen®.
   **Prior authorization is required for Retacrit and Epogen*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Retacrit (epoetin alfa-epbx), Epogen (epoetin alfa)	**Anemia due to CKD** 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® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
†Off-label indication

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): strong cytochrome P450 2C8 (CYP2C8) inhibitors such as gemfibrozil, uncontrolled hypertension

- Boxed warning(s): increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Anemia due to CKD	Not being treated with an erythropoiesis-stimulating agents (ESA): • Hemoglobin < 9 g/dL: 4 mg PO QD • Hemoglobin 9 - 10 g/dL: 2 mg PO QD • Hemoglobin > 10 g/dL: 1 mg PO QD Adults being switched from an ESA*: • EA ≤ 2,000/DA 20 - 30/M 30 - 40: 4 mg PO QD • EA > 2,000 to < 10,000/DA 30 - 150/M 40 - 180: 6 mg PO QD • EA ≥ 10,000 to < 20,000/DA 150 - 3000/M 180 - 360: 8 mg PO QD • EA ≥ 20,000/DA > 300/M > 360: 12 mg PO QD	Varies depending on indication and frequency of administration.

***** *EA – epoetin alfa, units/week; DA – darbepoetin alfa, mcg/4 weeks; M – Mircera, mcg/month*

VI. Product Availability

Tablets: 1 mg, 2 mg, 4 mg, 6 mg, 8 mg

VII. References

1. Jesduvroq Prescribing Information. Durham, NC: GlaxoSmithKline; February 2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216951s000lbl.pdf. Accessed March 15, 2023.
2. Clinical Pharmacology [database online]. Elsevier, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed February 1, 2023.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 1, 2023.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07/2023	