

Clinical Policy: Daprodustat (Jesduvroq)

Reference Number: CP.PHAR.628

Effective Date: 06.01.23

Last Review Date: 05.23

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation[®] 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 \geq 18 years;
3. Prescribed by or in consultation with a hematologist or nephrologist;
4. Member has received dialysis for \geq 4 months;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level \geq 100 mcg/L or serum transferrin saturation \geq 20%;
6. Pretreatment hemoglobin level of 8 to 11.5 g/dL;
7. Member meets one of the following (a or b):
 - a. Failure of Retacrit[®], unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Retacrit*
 - b. If Retacrit is unavailable due to shortage, failure of Epogen[®], unless contraindicated or clinically significant adverse effects are experienced.
**Prior authorization may be required for Epogen*

Approval duration:

Medicaid/HIM – 6 months

Commercial – 6 months or to member’s renewal period, whichever is longer

B. Other diagnoses/indications (must meet all):

1. Member meets one of the following (a or b):
 - a. One of the following (i or ii):
 - i. Failure of Retacrit, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Retacrit*
 - ii. If Retacrit is unavailable due to shortage, failure of Epogen, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Epogen*
 - b. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix D*);
2. Member meets one of the following (a or b):
 - a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
 - i. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - ii. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
 - b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2a above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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 $\geq 20\%$.

Approval duration:

Medicaid/HIM – 6 months

Commercial – 6 months or to member’s renewal period, whichever is longer

B. Other diagnoses/indications (must meet all):

1. Member meets one of the following (a or b):
 - a. One of the following (i or ii):
 - i. Failure of Retacrit, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Retacrit*
 - ii. If Retacrit is unavailable due to shortage, failure of Epogen, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Epogen*
 - b. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (see *Appendix D*);
2. Member meets one of the following (a or b):
 - a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (i or ii):
 - i. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - ii. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
 - b. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2a above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

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

Appendix D: States with Regulations against Redirections in Certain Oncology Settings

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions.
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.
LA	Yes	For stage 4 advanced, metastatic cancer or associated conditions. Exception if “clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.
NV	Yes	Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
OH	Yes	<i>*Applies to Commercial and HIM requests only*</i> For stage 4 metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes	For advanced metastatic cancer and associated conditions
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Anemia due to CKD	<p>Not being treated with an erythropoiesis-stimulating agents (ESA):</p> <ul style="list-style-type: none"> 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 <p>Adults being switched from an ESA*:</p> <ul style="list-style-type: none"> 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

- Jesduvroq Prescribing Information. Durham, NC: GlaxoSmithKline; February 2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216951s0001bl.pdf. Accessed March 15, 2023.
- Clinical Pharmacology [database online]. Elsevier, Inc.; 2023. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed February 1, 2023.
- Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 1, 2023.
- 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.	03.15.23	05.23

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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