MEDICAL MUTUAL®

Drug Policy

Policy:	Jesduvroq® (daprodustat tablets – GlaxoSmithKline)	Annual Review Date: 11/21/2023 Last Revised Date: 11/21/2023

OVERVIEW

Jesduvroq, a hypoxia-inducible factor prolyl hydroxylase inhibitor, is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least 4 months.[1]

Jesduvroq has not been shown to improve quality of life, fatigue, or patient well-being.[1] Jesduvroq is not indicated for the following uses:

- As a substitute for red blood cell (RBC) transfusions in those who require immediate correction of anemia.
- For the treatment of anemia of CKD in patients who are not on dialysis.

Also, it is recommended to evaluate the iron status in patients before and during Jesduvroq therapy.[1] Administer supplemental iron therapy when serum ferritin is < 100 mcg/mL or when serum transferrin saturation is < 20%. The majority of patients with CKD will require supplemental iron during the course of therapy. Do not target a hemoglobin level higher than 11.0 g/dL. If the hemoglobin level exceeds 12.0 g/dL, interrupt treatment with Jesduvroq. When the hemoglobin level is within the target range, treatment may be restarted at a lower level. Treatment with Jesduvroq should not be continued beyond 24 weeks of therapy if a clinically meaningful increase in hemoglobin level is not achieved.

POLICY STATEMENT

This policy involves the use of Jesduvroq. Prior authorization is recommended for pharmacy benefit coverage of Jesduvroq. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Jesduvroq as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Jesduvroq be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Jesduvroq is recommended in those who meet the following criteria:

1. **Anemia in a Patient with Chronic Kidney Disease who is on Dialysis.** Approve for the duration noted below if the patient meets one of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has been receiving dialysis for at least 4 consecutive months; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient meets BOTH of the following (1 and 2):
         - **(1)** Patient is currently receiving an erythropoiesis-stimulating agent AND transitioning to Jesduvroq; AND
           Note: Examples of erythropoiesis-stimulating agents include epoetin alfa products (e.g., Epogen, Procrit, or Retacrit intravenous or subcutaneous injection), Aranesp (darbepoetin alfa intravenous or subcutaneous injection), or Mircera (methoxy polyethylene glycol-epoetin beta intravenous or subcutaneous injection).
         - **(2)** Patient has a hemoglobin level ≤ 12.0 g/dL; OR
       - **b)** Patient meets BOTH of the following (1 and 2):
         - **(1)** Patient is NOT currently receiving an erythropoiesis-stimulating agent; AND
           Note: Examples of erythropoiesis-stimulating agents include epoetin alfa products (e.g., Epogen, Procrit, or Retacrit intravenous or subcutaneous injection), Aranesp (darbepoetin alfa intravenous or subcutaneous injection), or Mircera (methoxy polyethylene glycol-epoetin beta intravenous or subcutaneous injection).
         - **(2)** Patient has a baseline (prior to initiation of Jesduvroq) hemoglobin level < 11 g/dL; AND
     - **iv.** Patient meets one of the following (a or b):
       - **a)** Patient is currently receiving iron therapy; OR
       - **b)** According to the prescriber, patient has adequate iron stores; AND
     - **v.** The medication is prescribed by or in consultation with a nephrologist; OR
   - **B)** Patient is Continuing Therapy with Jesduvroq. Approve for 1 year if the patient meets the following (i, ii, iii, iv, v, and vi):
     Note: For a patient who has not received 6 months (24 weeks) of therapy or who is restarting therapy, refer to Initial Therapy criteria above.
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has been receiving dialysis for at least 4 consecutive months; AND
     - **iii.** Patient has a hemoglobin level ≤ 12.0 g/dL; AND
     - **iv.** Patient meets ONE of the following (a or b):
       - **a)** Patient is currently receiving iron therapy; OR
       - **b)** According to the prescriber, patient has adequate iron stores; AND
     - **v.** The medication is prescribed by or in consultation with a nephrologist; AND
     - **vi.** According to the prescriber, patient has experienced a response to therapy.
       Note: Examples of a response include an increase or stabilization in hemoglobin levels or a reduction or absence in red blood cell transfusions.

Initial Approval/ Extended Approval.

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A) *Initial Approval: 6 months*
B) *Extended Approval: 1 year*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Jesduvroq has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Anemia in a Patient with Chronic Kidney Disease who is NOT on Dialysis.** Jesduvroq is not indicated for use for the treatment of anemia of chronic kidney disease in patients who are not on dialysis.[1] The safety of Jesduvroq has not been established for the treatment of anemia due to CKD. In a large cardiovascular outcomes trial in adults with anemia of CKD who were not on dialysis (ASCEND-ND), an increased risk of cardiovascular mortality, stroke, thromboembolism, serious acute kidney injury, hospitalization for heart failure, and serious gastrointestinal erosions was observed in patients treated with Jesduvroq compared with erythropoietin-stimulating agent therapy.[3]

2. **Anemia Associated with Cancer.** Jesduvroq is not indicated for this use.[1]

3. **Active Malignancy.** Jesduvroq has not been studied and is not recommended in patients with active malignancies. Increased hypoxia inducible factor-1 levels may be associated with unfavorable effects on cancer growth.

4. **Anemia due to Acute Blood Loss.** Use of Jesduvroq is not appropriate in these types of situations. Jesduvroq is not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia.

5. **Concurrent Use with Erythropoiesis-Stimulating Agents.** Concomitant use is not recommended.
   Note: Examples of erythropoiesis-stimulating agents include epoetin alfa products (Procrit, Epogen, Retacrit intravenous or subcutaneous injection), Aranesp (darbepoetin alfa intravenous or subcutaneous injection), and Mircera (methyoxy polyethylene glycol-epoetin beta intravenous or subcutaneous injection).

6. **To Enhance Athletic Performance.** Jesduvroq is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

7. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Jesduvroq® tablets [prescribing information]. GlaxoSmithKline: Research Triangle Park, NC: February 2023.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012;2(Suppl):279-335.
3. Singh AJ, Carroll K, McMurray JJV, et al, for the ASCEND-ND Study Group. Daprodustat for the treatment of anemia in patients not undergoing dialysis. N Engl J Med. 2021;385(25):2313-2324.