# PRIOR AUTHORIZATION POLICY

**POLICY:** Nephrology - Jesduvroq Prior Authorization Policy
- Jesduvroq® (daprodustat tablets – GlaxoSmithKline)

**REVIEW DATE:** 09/27/2023

***INSTRUCTIONS FOR USE***

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## CIGNA NATIONAL FORMULARY COVERAGE:

### 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.

## Guidelines

Jesduvroq is not addressed in guidelines. The Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for anemia in CKD (2012) state that for adults with CKD 5D (kidney failure; on dialysis), erythropoiesis-stimulating agent (ESA) therapy should be used to avoid having the hemoglobin concentration fall below 9.0 g/dL by initiating ESAs when the hemoglobin level is between 9.0 and 10.0 g/dL.[2] The KDIGO guidelines state that individualization of therapy is reasonable as some patients may have improvement in quality of life at higher hemoglobin levels and ESA therapy may be started for hemoglobin levels above 10.0 g/dL. In general, ESAs should not be used to maintain hemoglobin levels above 11.5 g/dL for adult patients with CKD. Individualization of therapy will be necessary as some patients may have improvements in quality of life at a hemoglobin concentration above 11.5 g/dL and will be able to handle the risks. In adults, ESAs should not be given to intentionally increase hemoglobin levels above 13.0 g/dL.

## Safety

Jesduvroq has a Boxed Warning regarding an increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access.[1] Targeting a hemoglobin level greater than 11.0 g/dL is expected to further increase the risk of death and arterial venous thrombotic events, as occurs with ESAs, which also increase erythropoietin levels. No trial has identified a hemoglobin target level, dose of Jesduvroq, or dosing strategy that does not increase these risks. Use the lowest dose of Jesduvroq sufficient to reduce the need for RBC transfusions. If the hemoglobin level is > 12 g/dL, interrupt treatment with Jesduvroq. When the hemoglobin level is within the target range, treatment may be restarted.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Jesduvroq. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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, approval requires Jesduvroq to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Jesduvroq® (daprodustat tablets ( GlaxoSmithKline)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### FDA-Approved Indication

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.

## CONDITIONS NOT COVERED

- **Jesduvroq® (daprodustat tablets ( GlaxoSmithKline)**

**is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

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.

## 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.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| New Policy | -- | 09/27/2023 |