CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Jesduvroq (daprodustat)
BENEFIT TYPE	<Medical or Pharmacy>
STATUS	Prior Authorization Required

Jesduvroq, approved by the FDA in 2023, is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months. It has not been shown to improve quality of life, fatigue, or patient well-being, and is not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia, or for patients not on dialysis.
Erythropoiesis-stimulating agents (ESAs) such as epoetin alfa are the standard of care for treating anemia in CKD (especially in dialysis patients). Jesduvroq is the first approved HIF inhibitor and can be given orally, whereas ESA's must be injected. In the Phase 3 ASCEND trial, Jesduvroq was noninferior to ESA's in efficacy and cardiovascular (CV) safety outcomes. It has a boxed warning for increased risk of thrombotic vascular events. The lowest dose sufficient to reduce the need for red blood cell transfusions should be used.

Jesduvroq (daprodustat) will be considered for coverage when the following criteria are met:

Anemia of Chronic Kidney Disease (CKD)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has a diagnosis of anemia due to CKD; AND
4. Member has been receiving dialysis for at least 4 months; AND
5. Member's labs show hemoglobin level less than 10 g/dL in the last 30 days; AND
6. Member's labs show adequate iron stores with both of the following:
   a) Transferrin saturation is at least 20%
   b) Ferritin is at least 100 mcg/L; AND
7. Member has tried and failed an erythropoiesis stimulating agent (ESA) for at least 4 weeks; AND
8. Member does NOT have uncontrolled hypertension.
9. **Dosage allowed/Quantity limit:** See prescribing information. Starting doses depend on ESA status. Adjust based on hemoglobin levels; do not target hemoglobin >11 g/dL. Max dose 24 mg once daily. (QL: 90 tablets per 30 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show increased hemoglobin compared to baseline; AND
2. Current hemoglobin level does not exceed 12 g/dL.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Jesduvroq (daprodustat) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/10/2023	New policy for Jesduvroq created.

References:

1. Jesduvroq [prescribing information]. GlaxoSmithKline; 2023.
2. Singh AK, Carroll K, Perkovic V, et al. Daprodustat for the Treatment of Anemia in Patients Undergoing Dialysis. *N Engl J Med*. 2021;385(25):2325-2335. doi:10.1056/NEJMoa2113379
3. Kliger AS, Foley RN, Goldfarb DS, et al. KDOQI US commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. *Am J Kidney Dis*. 2013;62(5):849-859. doi:10.1053/j.ajkd.2013.06.008

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