UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2321-1
Program	Prior Authorization/Medical Necessity
Medication	Jesduvroq® (daprodustat)
P&T Approval Date	1/2024
Effective Date	4/1/2024

1. Background:

Jesduvroq (daprodustat) 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.

The treatment of anemia includes intravenous (IV) iron and/or treatment with either an erythropoiesis-stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] or a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF PHI) [e.g., Jesduvroq (daprodustat)].

Limitations of Use

- Jesduvroq has not been shown to improve quality of life, fatigue, or patient well-being.
- Jesduvroq is not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia or in patients not on dialysis.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Jesduvroq** will be approved based on **all** of the following criteria:

   a. Diagnosis of anemia due to chronic kidney disease (CKD)

   -AND-

   b. Patient has been receiving dialysis for at least four months

   -AND-

   c. **Both** of the following:

      (1) Ferritin greater than 100 mcg/L
      (2) Transferrin saturation (TSAT) greater than 20%

   -AND-

   d. Hemoglobin level less than 11 g/dL

   -AND-

e. Trial and failure, contraindication or intolerance to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

-AND-

f. Prescribed by or in consultation with **one** of the following:

(1) Hematologist
(2) Nephrologist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Jesduvroq** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response to Jesduvroq therapy (e.g., clinically meaningful increase in hemoglobin level)

-AND-

b. Adequate iron stores confirmed by **both** of the following:

(1) Ferritin greater than 100 mcg/L
(2) Transferrin saturation (TSAT) greater than 20%

-AND-

c. Hemoglobin level does not exceed 12 g/dL

-AND-

d. Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

-AND-

e. Prescribed by or in consultation with **one** of the following:

(1) Hematologist
(2) Nephrologist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class

4. References:

1. Jesduvroq [package insert]. Durham, NC: GlaxoSmithKline; August 2023.
2. Akizawa T, Nangaku M, Yonekawa T, et al. Efficacy and Safety of Daprodustat Compared with Darbepoetin Alfa in Japanese Hemodialysis Patients with Anemia: A Randomized, Double-Blind, Phase 3 Trial. *Clin J Am Soc Nephrol*. 2020;15(8):1155-1165. doi:10.2215/CJN.16011219
3. Ketteler M, Block GA, Evenepoel P, Fukagawa M, Herzog CA, McCann L, Moe SM, Shroff R, Tonelli MA, Toussaint ND, Vervloet MG, Leonard MB. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD). Ann Intern Med. 2018 Mar 20;168(6):422-430.

Program	Prior Authorization/Medical Necessity - Jesduvroq (daprodustat)
Change Control	
1/2024	New program.