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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	October 13, 2023
Subject:	Jesduvroq	**Page:**	1 of 5

Last Review Date: December 13, 2024

Jesduvroq

Description

Jesduvroq (daprodustat)

Background
Jesduvroq (daprodustat) is a reversible inhibitor of hypoxia-inducible factor prolyl hydroxlase 1 (HIF PH1), HIF PH2, and HIF PH3. This activity results in the stabilization and nuclear accumulation of HIF-1α and HIF-2α transcription factors, leading to increased transcription of the HIF-responsive genes, including erythropoietin (1).

Regulatory Status
FDA-approved indication: Jesduvroq is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four months (1).

Limitations of Use: (1)
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
- In patients not on dialysis

Jesduvroq has a boxed warning of increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access. A target hemoglobin level greater than 11 g/dL is expected to increase the risk of death and arterial and venous thrombotic events. Use the lowest dose of Jesduvroq sufficient to reduce the need for red blood cell transfusions (1).

Jesduvroq is contraindicated in patients receiving a strong cytochrome P450 2C8 (CYP2C8) inhibitor and patients with uncontrolled hypertension (1).

Jesduvroq has been associated with additional cardiologic adverse effects. This includes an increased risk of hospitalization for heart failure in patients with a history of heart failure, and worsening hypertension. Blood pressure should be monitored periodically, and anti-hypertensive therapy should be initiated as needed (1).

Gastric or esophageal erosions and gastrointestinal bleeding have been reported in patients taking Jesduvroq (1).

Jesduvroq may have unfavorable effects on cancer growth. Therefore, the use of this medication is not recommended if the patient has active malignancy (1).

The safety and effectiveness of Jesduvroq pediatric patients less than 18 years of age have not been established (1).

Related policies

Vafseo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Jesduvroq may be considered **medically necessary** if the conditions indicated below are met.

Jesduvroq may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic kidney disease

AND ALL of the following:

a. Patient has been on dialysis for at least four months prior to treatment
b. Patient is currently on dialysis
c. Hemoglobin ≤11 g/dL
d. Serum ferritin ≥ 100 ng/ml (labs must have been taken within the last 3 months)
e. Patient requires red blood cell (RBC) transfusions to manage anemia
f. Patient has had an inadequate treatment response, intolerance, or contraindication to an erythropoiesis stimulating agent (e.g., darbepoetin alfa, epoetin alfa)
g. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Jesduvroq therapy is appropriate

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic kidney disease

AND ALL of the following:

a. Patient is currently on dialysis
b. Hemoglobin ≤11 g/dL
c. Serum ferritin ≥ 100 ng/ml (labs must have been taken within the last 3 months)
d. The need for red blood cell (RBC) transfusion has reduced since initiating therapy
e. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Jesduvroq therapy is appropriate

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Jesduvroq is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to CKD in patients who have been receiving dialysis for at least four months. Jesduvroq is not indicated for the treatment of anemia of CKD in patients who are not dialysis-dependent. Jesduvroq has a box warning regarding an increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access. Treatment can cause worsening hypertension and heart failure. Gastric or esophageal erosions and gastrointestinal bleeding have been reported. Jesduvroq is not recommended if the patient has active malignancy due to unfavorable effects on cancer growth The safety and effectiveness of Jesduvroq in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Jesduvroq while maintaining optimal therapeutic outcomes.

References

1. Jesduvroq [package insert]. Durham, NC: GlaxoSmithKline; August 2023.

Policy History

Date	Action
October 2023	Addition to PA
December 2023	Annual review
March 2024	Annual review
June 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.