

STANDARD MEDICARE PART B MANAGEMENT

JESDUVROQ (daprodustat)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Jesduvroq is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four months.

Limitations of Use:

- A. Jesduvroq has not been shown to improve quality of life, fatigue, or patient well-being.
- B. Jesduvroq is not indicated for use:
 - 1. As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
 - 2. For treatment of anemia of chronic kidney disease in patients who are not on dialysis.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion.

Anemia due to Chronic Kidney Disease (CKD)

Authorization of 12 weeks may be granted for the treatment of anemia due to chronic kidney disease in members receiving dialysis for at least 4 months with a pretreatment hemoglobin of less than or equal to 11 g/dL.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 weeks may be granted when all of the following criteria are met:

- 1. The member is currently receiving therapy with Jesduvroq.
- 2. Jesduvroq is being used to treat anemia due to chronic kidney disease (CKD).
- 3. Jesduvroq has been effective for treating the diagnosis or condition.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Jesduvroq.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Jesduvroq are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications (anemia due to chronic kidney disease) can be found in the manufacturer's prescribing information.

VI. REFERENCES

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

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