

Medical Policy:

Jesduvroq (daprodustat) oral tablets

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.402	November 9, 2023	November 9, 2023

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Length of Authorization

Initial: 6 months

Continuation: 12 months

Dosing Limits [Medical Benefit]

Maximum: 24mg once daily

Guideline
I. Initial

1. Anemia in a Patient with Chronic Kidney Disease who is on Dialysis. Approve if the patient meets the following (A, B, C, and D):

- A. Patient is ≥ 18 years of age; AND
- B. Patient has been receiving dialysis for at least 4 consecutive months; AND
- C. Patient meets **ONE** of the following (i or ii):

- i. Patient meets **BOTH** of the following (a <u>and</u> b):
 - a. Patient is currently receiving an erythropoiesis-stimulating agent **AND** transitioning to Jesduvroq; **AND**

<u>Note</u>: 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).

- b. Patient has a hemoglobin level ≤ 12.0 g/dL; **OR**
- ii. Patient meets **BOTH** of the following (a <u>and</u> b):
 - a. Patient is NOT currently receiving an erythropoiesis-stimulating agent; AND

<u>Note</u>: 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).

- b. Patient has a baseline (prior to initiation of Jesduvrog) hemoglobin level < 11 g/dL; AND
- D. Patient meets one of the following (i or ii):
 - i. Patient is currently receiving iron therapy; **OR**
 - ii. According to the prescriber, patient has adequate iron stores

II. Renewal

1. Anemia in a Patient with Chronic Kidney Disease who is on Dialysis.

Approve if the patient meets the following (A, B, C, D, and E):

<u>Note</u>: For a patient who has not received 6 months (24 weeks) of therapy or who is restarting therapy, refer to Initial Therapy criteria above.

- A. Patient is ≥ 18 years of age; **AND**
- B. Patient has been receiving dialysis for at least 4 consecutive months; AND
- C. Patient has a hemoglobin level ≤ 12.0 g/dL; AND
- D. Patient meets ONE of the following (i or ii):
 - i. Patient is currently receiving iron therapy; **OR**
 - ii. According to the prescriber, patient has adequate iron stores; AND
- E. 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

Applicable Procedure Codes

Code	Description	
J0889	Daprodustat, oral, 1 mg, (for esrd on dialysis)	

Applicable NDCs

Code	Description
00173-0914-13	JESDUVROQ 8MG Tablet
00173-0911-13	JESDUVROQ 6MG Tablet
00173-0903-13	JESDUVROQ 2MG Tablet
00173-0906-13	JESDUVROQ 4MG Tablet

ICD-10 Diagnoses

Code	Description
N18.9	Chronic Kidney Disease, unspecified
N18.6	ESRD
D63.1	Anemia in chronic kidney disease

Revision History

Company(ies)	DATE	REVISION
EmblemHealth &	10/13/2023	New Policy
ConnectiCare		

References

1. Product Information: JESDUVROQ oral tablets, daprodustat oral tablets. GlaxoSmithKline (per FDA), Durham, NC, 2023.