CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 5780-A |

# Specialty Guideline Management Jesduvroq

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Jesduvroq | daprodustat |

## 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 Indication1

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.

All other indications are considered experimental/investigational and not medically necessary.

## Coverage Criteria

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before starting Jesduvroq. Members may not use Jesduvroq concomitantly with erythropoiesis stimulating agents.

### Anemia Due to Chronic Kidney Disease (CKD)1-4

Authorization of 12 weeks may be granted for treatment of anemia due to chronic kidney disease in adult members when both of the following criteria are met:

* The member has been receiving dialysis for at least four months.
* The pretreatment hemoglobin level is less than or equal to 11 grams per deciliter (g/dL).

## Continuation of Therapy1-3,5

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before continuation of treatment with Jesduvroq. Members may not use Jesduvroq concomitantly with erythropoiesis stimulating agents.

All members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of Jesduvroq treatment must show a response with a rise in hemoglobin of greater than or equal to 1 g/dL. Members who have completed less than 12 weeks of Jesduvroq treatment and have not yet responded with a rise in hemoglobin of greater than or equal to 1 g/dL may be granted authorization for up to 12 weeks to allow for sufficient time to demonstrate a response.

Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in adult members receiving dialysis with current hemoglobin less than 12 g/dL.

## References

1. Jesduvroq [package insert]. Durham, NC: GlaxoSmithKline; August 2023.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete\_ashp [available with subscription]. Accessed September 5, 2024.
3. Singh AK, Carroll K, Perkovic V, et al. Daprodustat for the Treatment of Anemia in Patients Undergoing Dialysis. N Engl J Med. 2021 Dec 16;385(25):2325-2335. doi: 10.1056/NEJMoa2113379. Epub 2021 Nov 5.
4. Singh AK, Blackorby A, Cizman B, et al. Study design and baseline characteristics of patients on dialysis in the ASCEND-D trial. Nephrol Dial Transplant. 2022 Apr 25;37(5):960-972. doi: 10.1093/ndt/gfab065.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012;Suppl 2:279-335.