**Methoxy Polyethylene Glycol-Epoetin Beta (Mircera®)**

**IMPORTANT REMINDER**

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:**
**POLICY**

**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

Mircera is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in:

- Adult patients on dialysis and adult patients not on dialysis.
- Pediatric patients 3 months ~~5~~ to 17 years of age on dialysis or not on dialysis ~~hemodialysis~~ who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.

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

**COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~**

Note: Requirements regarding hemoglobin level exclude values due to 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 Mircera. Members may not use Mircera concomitantly with other erythropoiesis stimulating agents.

**Anemia Due to Chronic Kidney Disease (CKD)**

Authorization of 12 weeks may be granted for the treatment of anemia due to CKD ~~chronic kidney disease~~ in members with pretreatment hemoglobin less than ~~<~~ 10 grams per deciliter (g/dL).

Authorization of 12 weeks may be granted for the treatment of anemia due to CKD in pediatric members 3 months to 17 years of age who are converting from another ESA after their hemoglobin level was stabilized (e.g., Hgb level of 10 to 12 g/dL) with an ESA.

**CONTINUATION OF THERAPY**

Note: Requirements regarding current hemoglobin level exclude values due to 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% with the prior 3 months) or are receiving iron therapy before

continuation of treatment with Mircera. Members may not use Mircera concomitantly with other erythropoiesis stimulating agents.

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

**Anemia Due to Chronic Kidney Disease (CKD)**

Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in members with current hemoglobin less than ~~<~~ 12 g/dL ~~and the member has shown a response to therapy with a rise in hemoglobin of ≥ 1 g/dL after at least 12 weeks of ESA therapy.~~
~~Authorization of up to 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in members who have not completed 12 weeks of ESA therapy.~~

## APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

## ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

## REFERENCES

1. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; April 2024.
2. 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.

## EFFECTIVE DATE

## ID_CHS