

Effective date: 9/1/2020
Reviewed: 7/2020, 7/2021, 6/2022, 4/2023, 5/2024, 4/2025
Scope: Medicaid

MIRCERA (methoxy polyethylene glycol-epoetin beta)

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

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 to 17 years of age on dialysis and not on dialysis 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.

II. 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 or are receiving iron therapy before starting Mircera. Members may not use Mircera concomitantly with other erythropoiesis stimulating agents. **The member must have documentation that they have tried and failed or have a contraindication to Retacrit**

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 with pretreatment hemoglobin < 10 g/dL (documentation provided).

Authorization of 12 weeks may be granted for the treatment of anemia due to chronic kidney disease in pediatric members 3 months to 17 years of age who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized (e.g., Hgb level of 10-12 g/dl) with an ESA (documentation provided).

III. CONTINUATION OF THERAPY

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

Anemia Due to Chronic Kidney Disease (CKD)

1. Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in members with current hemoglobin < 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 (documentation provided)..
2. 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.

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IV. REFERENCES

1. Mircera [package insert]. South San Francisco, CA: Hoffmann-La Roche Inc.; June 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.
3. National Kidney Foundation. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target.
http://www2.kidney.org/professionals/KDOQI/guidelines_anemiaUP/. Accessed September 15, 2019