



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Mircera

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Effective Date: 3/14/2025

Last Review Date: 2/20/2025

Applies to: ☒ Illinois

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Mircera under the patient's prescription drug benefit.

Description:

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 or 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.

Applicable Drug List:

Non-Preferred Agent:

Mircera

Policy/Guideline:

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 chronic kidney disease in members with pretreatment hemoglobin < 10 g/dL AND patient is unable to take Epogen and Procrit for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

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



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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

Approval Duration and Quantity Restrictions:

Approval: 12 weeks

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.