Reference number(s)
4462-A

Standard Medicare Part B Management Mircera

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
Mircera	methoxy polyethylene glycol-epoetin beta

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[1]

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 (Hgb) level was stabilized with an ESA.

Limitations of Use

Mircera is not indicated and is not recommended:

- In the treatment of anemia due to cancer chemotherapy
- As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia

Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life.

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Note: Use in members on dialysis is covered under the Medicare Part B dialysis benefit and is excluded from coverage under this policy.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Note: Requirements regarding hemoglobin level exclude values due to recent transfusion.

Anemia Due to Chronic Kidney Disease (CKD)[1,2]

Authorization of 12 weeks may be granted for the treatment of anemia due to CKD in adult members not receiving dialysis with a pretreatment hemoglobin of less than 10 grams per deciliter (g/dL) or a hematocrit of less than 30%.

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 not receiving dialysis 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 (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 weeks may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Mircera.
- Mircera is being used to treat anemia due to chronic kidney disease (CKD).
- Mircera has been effective for treating the diagnosis or condition.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Mircera.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service-Drug Information (AHFS-DI)
    - Lexi-Drugs

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    - Clinical Pharmacology
- Kidney Disease: Improving Global Outcomes (KDIGO) 2012 Clinical Practice Guideline for Anemia for Chronic Kidney Disease

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Mircera are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing 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.

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