Reference number(s)
5565-A

Jurisdiction Specific Medicare Part B 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

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Anemia related to end-stage renal disease (ESRD) and Stages IIIb, IV and V chronic kidney disease (CKD)
- Anemia of chronic kidney disease (CKD) in a pediatric member 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.

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: The following causes of anemia should be considered, documented, and corrected before starting or continuing ESA therapy for any of the covered indications: iron deficiency; underlying infection, inflammatory or malignant processes; underlying hematological disease; hemolysis; vitamin deficiencies (e.g., folic acid or B12); blood loss- overt or occult; aluminum intoxication; osteitis fibrosis cystica; or pure red blood cell aplasia.

Anemia of end Stage Renal Disease (ESRD) Adult Members on Dialysis

Authorization of 12 weeks may be granted for treatment of anemia of ESRD in an adult member on dialysis when all of the following criteria are met:

- Member has a diagnosis of end stage renal disease.
- Hemoglobin (Hgb) less than 10 grams per deciliter (g/dL) or hematocrit (HCT) less than 30% at initiation of therapy.
- The provider will document the most recent creatinine within the past month prior to initiation or next dosing of ESA.

Anemia of Chronic Kidney Disease (CKD) in Adult Members not on Dialysis

Authorization of 12 weeks may be granted for treatment of anemia of CKD in an adult member not on dialysis when all of the following criteria are met:

- Hgb less than 10 g/dL or HCT less than 30% at initiation of therapy.
- Glomerular filtration rate (GFR) less than 45 mL/min/1.73m2.
- The provider will document the most recent creatinine within the past month prior to initiation or next dosing of ESA.

Anemia of Chronic Kidney Disease (CKD) in Pediatric Members 3 Months to 17 Years of Age

Authorization of 12 weeks may be granted for treatment of anemia of CKD in a pediatric member 3 months to 17 years of age who are converting from another ESA after their Hgb level was not stabilized (Hgb level of 10 to 12 g/dL) with an ESA.

Continuation of Therapy

Note: The following causes of anemia should be considered, documented, and corrected before starting or continuing ESA therapy for any of the covered indications: iron deficiency; underlying infection, inflammatory or malignant processes; underlying hematological disease; hemolysis; vitamin deficiencies (e.g., folic acid or B12); blood loss- overt or occult; aluminum intoxication; osteitis fibrosis cystica; or pure red blood cell aplasia.

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

- The goal of therapy is to maintain a stable Hgb and HCT, with target ranges of 10-12 g/dL and 30-36% respectively.
- The provider will document the most recent creatinine within the past month prior to next dosing of ESA.

Dosage and Administration

The starting dose and subsequent dose adjustments must be in accordance with FDA-approved labeling or dosing provided in Billing and Coding: Erythropoiesis Stimulating Agents (A58982) or LCD – Erythropoiesis Stimulating Agents (L39237). Doses must be titrated according to the patient's response.

References

1. Erythropoiesis Stimulating Agents LCD (L39237) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 11, 2024.
2. Billing and Coding: Erythropoiesis Stimulating Agents (ESA) (A58982) Version R2. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 11, 2024.
3. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; April 2024.