Reference number(s)
5194-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 of end stage renal disease (ESRD) in an adult on dialysis
- Anemia of chronic kidney disease (CKD) in an adult not on dialysis
- Anemia of chronic kidney disease (CKD) in a pediatric member 3 months to 17 years of age on dialysis or not on dialysis who is 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

Anemia of end stage renal disease (ESRD) in adults on dialysis

Authorization of 12 weeks may be granted for the treatment of anemia in an adult member with ESRD who is on dialysis when the pretreatment hemoglobin level is less than 10 g/dL (or hematocrit [HCT] is less than 30%).

Anemia of chronic kidney disease (CKD) in adults not on dialysis

Authorization of 12 weeks may be granted for the treatment of anemia in an adult member with CKD who is not on dialysis when the pretreatment Hgb level is less than 10 g/dL (or HCT less than 30%) and the member meets one of the following criteria:

- Serum creatinine greater than or equal to 3 mg/dL
- Creatinine clearance less than 60 mL/min
- Glomerular filtration rate (GFR) less than 60 mL/min/1.73m^2

Anemia of chronic kidney disease (CKD) in pediatric members 3 months to 17 years of age

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

Continuation of Therapy

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

- Doses must be titrated according to the patient's response. ESA therapy need not be stopped completely simply due to the achievement of the target Hgb and/or HCT. However, judicious, appropriately timed dose adjustments are expected to prevent inappropriate increases in Hgb and HCT levels.
- Continued use and determination of dosage level must be medically reasonable and necessary.

References

1. Erythropoiesis Stimulating Agents (ESAs) LCD (L34633) Version R24. Available at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx. Accessed September 11, 2024.
2. Billing and Coding: Erythropoiesis Stimulating Agents (A56795) Version R12. Available at: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx. Accessed September 11, 2024.
3. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; April 2024.