Mircera® (methoxy polyethylene glycol-epoetin beta) Injection

When requesting Mircera® (methoxy polyethylene glycol-epoetin beta) injection, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Mircera is indicated for the treatment of anemia associated with chronic kidney disease 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.

Coverage Guidelines

Anemia in Patients with Chronic Kidney Disease (CKD)

- An individual is on dialysis.

  OR

- An individual not on dialysis must meet **all** of the following criteria:
  - Has adequate iron stores or is currently receiving iron therapy;
  - *For initial treatment (individual not currently receiving an ESA [e.g., an epoetin alfa product {e.g., Epogen, Procrit, or Retacrit}, a darbepoetin alfa product {e.g., Aranesp}, a methoxy polyethylene glycol-epoetin beta product {e.g., Mircera}]):*
    - Is ≥ 18 years of age; AND
    - Has a hemoglobin < 10.0 g/dL;
  - *For an individual currently receiving an ESA (e.g., an epoetin alfa product [e.g., Epogen, Procrit, or Retacrit], a darbepoetin alfa product [e.g., Aranesp], a methoxy polyethylene glycol-epoetin beta product [e.g., Mircera])*:
    - Has hemoglobin ≤ 12.0 g/dL; AND
    - If less than 18 years of age, hemoglobin level has been stabilized with an ESA.

Approval Duration: 12 months

Dosing Recommendations

In adult patients, Mircera is administered by subcutaneous or intravenous injection.
For initial treatment (patients not currently treated with an ESA):

- CKD patients on dialysis: 0.6 mcg/kg body weight administered once every 2 weeks.
- CKD patients not on dialysis: 1.2 mcg/kg body weight administered once every month as a single subcutaneous injection. Alternatively, a starting dose of 0.6 mcg/kg body weight may be administered once every 2 weeks as a single intravenous or subcutaneous injection.

For conversion from another ESA: dosed once monthly or once every 2 weeks based on total weekly epoetin alfa or darbepoetin alfa dose at time of conversion.

In pediatric patients, Mircera is administered by subcutaneous or intravenous injection.

- Prefilled syringes are not designed for administration of partial doses. Pediatric patients requiring doses of less than 30 mcg should not be treated with Mircera
- In patients < 6 years of age, maintain the same route of administration as the previous ESA when switching from another ESA to Mircera.
- Administer once every 4 weeks to those patients whose hemoglobin level has been stabilized by treatment with an ESA. The starting dose of Mircera is calculated based on the total weekly dose of ESA at the time of conversion.

References

1. Mircera® solution for injection [prescribing information]. Basking Ridge, NJ: Vifor Pharma; 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; 2(Suppl):279-335.