

Mircera® (methoxy polyethylene glycol-epoetin beta) Injection

When requesting Mircera® (methoxy polyethylene glycol-epoetin beta) injection, the individual requiring treatment must be diagnosed with 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 5 to 17 years of age on hemodialysis 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 is not on dialysis and must meet the following criteria:
 - Is 18 years of age or older
 - Has adequate iron stores OR is currently receiving iron therapy
 - *For an initial authorization* – must have a hemoglobin <10.0 g/dL
 - *For individuals who are currently receiving an erythropoiesis-stimulating agent (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])* – must have a hemoglobin <11.5 g/dL

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 intravenous injection only.

- Conversion from another ESA: dosed once every 4 weeks based on total weekly epoetin alfa or darbepoetin alfa dose at time of conversion

References

1. Mircera® solution for injection [prescribing information]. Basking Ridge, NJ: Vifor Pharma; March 2023.
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.