

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

- Treatment of anemia associated with chronic kidney disease (CKD) in adult individuals on dialysis and individuals not on dialysis
- Treatment of anemia associated with chronic kidney disease (CKD) in pediatric patients on hemodialysis

Coverage Guidelines

Anemia in Patients with Chronic Kidney Disease (CKD) who are on dialysis:

The patient must meet the following criteria (A or B):

A) Initial therapy. Approve if the patient meets the following criteria (i, ii, and iii):

- i. The patient is ≥ 5 years of age; AND
- ii. The patient meets one of the following (a or b)
 - a. The patient is ≥ 18 years of age with a hemoglobin (Hgb) < 10 g/dL; OR
 - b. The patient is < 18 years of age with a hemoglobin ≤ 11 g/dL; AND
- iii. The patient meets one of the following (a or b):
 - a. The patient is currently receiving iron therapy; OR
 - b. The patient has adequate iron stores.

B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA). Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). Approve if the patient meets the following criteria (i, ii, and iii):

- i. The patient is ≥ 5 years of age; AND
- ii. The patient meets one of the following (a or b):
 - a. The patient is ≥ 18 years of age with a hemoglobin < 11.5 g/dL; OR
 - b. The patient is < 18 years of age with a hemoglobin ≤ 12 g/dL; AND
- iii. The patient meets one of the following (a or b):
 - a. The patient is currently receiving iron therapy; OR
 - b. The patient has adequate iron stores.

Approval Duration: 12 months

Anemia in Patients with Chronic Kidney Disease (CKD) who are not on dialysis:

The patient must meet the following criteria (A or B)

- A) Initial Therapy.** Approve if the patient meets the following criteria (i, ii, and iii)
- The patient has a hemoglobin < 10 g/dL; AND
 - The patient is $\geq$ 18 years of age; AND
 - The patient meets one of the following criteria (a or b):
 - The patient is currently receiving iron therapy; OR
 - The patient has adequate iron stores.
- B) Patient is currently receiving an erythropoiesis-stimulating agent (ESA).** Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). Approve if the patient meets the following criteria (i, ii, and iii):
- The patient has a hemoglobin < 11.5 g/dL; AND
 - The patient is $\geq$ 18 years of age; AND
 - The patient meets one of the following (a or b):
 - The patient is currently receiving iron therapy; OR
 - The patient has adequate iron stores.

Approval Duration: 12 months

Dosing Recommendations

Anemia in Patients with Chronic Kidney disease (CKD) who are on Dialysis:

The patient must meet the following criteria (A or B):

- A) Patient $\geq$ 18 years of age.** Approve if the dose meets the following (i or ii):
- The dose meets the following (a and b)
 - Each dose is $\leq$ 180 mcg; AND
 - Each dose is given no more frequently than once every 2 weeks; OR
 - The dose meets the following (a and b):
 - Each dose is $\leq$ 360 mcg; AND
 - Each dose is given no more frequently than once monthly; OR
- B) Patients $\geq$ 5 years to < 18 years of age.** Approve if the dose meets the following (i and ii)
- Each dose is given no more frequently than once every 4 weeks; AND
 - The dose meets one of the following (a or b):
 - Conversion from epoetin alfa product; 4 multiplied by previous weekly epoetin alfa dose (units) divided by 125; OR
 - Conversion from darbepoetin alfa product; 4 multiplied by previous weekly darbepoetin alfa dose (mcg) divided by 0.55.

Anemia in Patients with Chronic Kidney Disease (CKD) who are not on Dialysis:

The patient must meet the following criteria (A or B):

- A) Approve if the dose meets the following (i and ii):**
- Each dose is $\leq$ 180 mcg; AND
 - Each dose is given no more frequently than once every 2; OR

- B)** Approve if the dose meets the following (i and ii):
- i. Each dose is < 360 mcg; AND
 - ii. Each dose is given no more frequently than once monthly.

References

1. Mircera® solution for injection [prescribing information]. Basking Ridge, NJ: Vifor Pharma; June 2018.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Inter.* 2012; 2(Suppl):279-335. Available at: http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf. Accessed on June 18, 2018.
3. Locatelli F, Choukroun G, Truman M, et al. Once-monthly continuous erythropoietin receptor activator (C.E.R.A.) in patients with hemodialysis-dependent chronic kidney disease: pooled data from Phase III trial. *Adv Ther.* 2016; 33:610-625.
4. Saglimbene VM, Palmer SC, Ruospo M, et al. Continuous erythropoiesis receptor activator (CERA) for the anemia of chronic kidney disease. *Cochrane Database Syst Rev.* 2017 Aug 7; 8:CD009904.
5. Fischbach M, Wuhl E, Reigner SCM, et al. Efficacy and long-term safety of C.E.R.A. maintenance in pediatric hemodialysis patients with anemia of CKD. *Clin J Am Soc Nephrol.* 2018; 13(1):81-90.