

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

Approved Off-Label Compendial Uses

None

Coverage Guidelines

Anemia associated with chronic kidney disease in adults (greater than or equal to 18 years of age)

Initial

- The pretreatment hemoglobin (Hgb) level is less than 10 g/dL
- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- All other causes of anemia are ruled out or corrected (e.g., vitamin deficiency, metabolic conditions, bleeding, etc.)
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia (PRCA) that begins after treatment with Mircera® (methoxy polyethylene glycol-epoetin beta) or other erythropoietin protein drugs

Reauthorization

- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- The patient adequately responded to Mircera therapy (i.e. an increase in hemoglobin of at least 1 g/dL after at least 12 weeks of therapy)
- The current hemoglobin level is less than 12 g/dL
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia (PRCA) that begins after treatment with Mircera® (methoxy polyethylene glycol-epoetin beta) or other erythropoietin protein drugs

Anemia associate with chronic kidney disease in pediatric patients on hemodialysis

Initial

- Patient's age is between 5 to 17 years old
- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- Patient is on hemodialysis
- The patient is converting form another ESA agent after hemoglobin level is stabilized
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia (PRCA) that begins after treatment with Mircera® (methoxy polyethylene glycol-epoetin beta) or other erythropoietin protein drugs

Reauthorization:

- Patient's age is between 5 to 17 years old
- Serum ferritin is greater than or equal to 100 mcg/L OR serum transferrin saturation is greater than or equal to 20% OR individual is receiving supplemental iron
- The patient has adequately responded to Mircera therapy and/or hemoglobin level is stabilized
- The current hemoglobin level is less than 12 g/dL
- The individual does **not** have any of the following conditions:
 - Uncontrolled hypertension
 - Pure red cell aplasia (PRCA) that begins after treatment with Mircera® (methoxy polyethylene glycol-epoetin beta) or other erythropoietin protein drugs

Approval (initial and reauthorization) duration is 6 months

Dosing Recommendations

- Adult with or without dialysis:
 - o Initial treatment: 0.6 mcg/kg once every two weeks
- Pediatric patients on hemodialysis:
 - o Based on total weekly ESA dose at the time of conversion

References

1. Mircera® prescribing information. Switzerland: Vifor (International) Inc.: June 2018. Accessed June 18, 2018.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed June 18, 2018.