CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Mircera (methoxy polyethylene glycol-epoetin beta)
BILLING CODE	Medical: J0888 (non-ESRD) Pharmacy: Must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Mircera is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and adult patients not on dialysis and pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA. Mircera is longer acting than epoetin and darbepoetin and can be administered less frequently. ESAs are the standard of care for treating anemia in CKD (especially in dialysis patients), reducing the need for blood transfusions. A boxed warning states ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence. The lowest sufficient dose should be used.

Mircera (methoxy polyethylene glycol-epoetin beta) will be considered for coverage when the following criteria are met:

Anemia due to Chronic Kidney Disease (CKD)

For **initial** authorization:

1. Member is at least 5 years of age and on hemodialysis OR at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has a diagnosis of anemia due to CKD; AND
4. Member's labs show adequate iron stores with both of the following:
   a) Transferrin saturation is at least 20%
   b) Ferritin is at least 100 mcg/L; AND
5. Labs must show one of the following within the last 30 days:
   a) Adults: Hemoglobin ≤10 g/dL
   b) Pediatrics 5 to 17 years of age: Member is converting from another ESA and has a stabilized hemoglobin level (e.g., 10-12 g/dL); AND
6. Member does NOT have uncontrolled hypertension.
7. **Dosage allowed/Quantity limit**: Recommended starting dose for adults: 0.6 mcg/kg IV or subQ once every 2 weeks; once hemoglobin is stable, may administer once monthly at twice that of the every 2 week dose. Pediatrics 5 to 17 years of age: IV once every 4 weeks according to table in prescribing information for switching from another ESA.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Labs must show stabilized or increased hemoglobin level compared to baseline, not to exceed 11.5 g/dL (12 g/dL for pediatrics); AND
2. Red blood cell transfusions are not required or the number of transfusions has decreased compared to baseline; AND
3. Member has adequate iron stores or is on iron therapy; AND
4. Member has not developed pure red cell aplasia (PRCA).

If all the above requirements are met, the medication will be approved for an additional 6 months.

CareSource considers Mircera (methoxy polyethylene glycol-epoetin beta) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/28/2022	New policy for Mircera created.

References:

1. Mircera [prescribing information]. Vifor Pharma; 2019.
2. Kliger AS, Foley RN, Goldfarb DS, et al. KDOQI US commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. *Am J Kidney Dis*. 2013;62(5):849-859. doi:10.1053/j.ajkd.2013.06.008
3. Palmer SC, Saglimbene V, Mavridis D, et al. Erythropoiesis-stimulating agents for anaemia in adults with chronic kidney disease: a network meta-analysis. *Cochrane Database Syst Rev*. 2014;2014(12):CD010590. Published 2014 Dec 8. doi:10.1002/14651858.CD010590.pub2

Effective date: 04/01/2023
Revised date: 09/28/2022