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PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Mircera (methoxy polyethylene glycol-epoetin beta)
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 3 months to 17 years of age on dialysis or not on dialysis 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 3 months 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 3 months 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**: See prescribing information for details.
   -Recommended starting dose for adults on dialysis not currently on an ESA: 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.
   -Recommended starting dose for adults NOT on dialysis not currently on an ESA: 1.2 mcg/kg subQ once a month, or 0.6 mcg/kg IV or subQ every two weeks; once hemoglobin is stable, may administer once monthly at twice that of the every 2-week dose.

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-Pediatrics 3 months 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 12 months.

HAP 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.
03/19/2025	Updated references. Increased renewal duration from 6 months to 12 months. Updated minimum age from 5 years to 3 months. Removed requirement for peds to be on dialysis. Updated dosing.

References:

1. Mircera [prescribing information]. Vifor Pharma; 2024.
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. Chung EY, Palmer SC, Saglimbene VM, Craig JC, Tonelli M, Strippoli GF. Erythropoiesis-stimulating agents for anaemia in adults with chronic kidney disease: a network meta-analysis. Cochrane Database Syst Rev. 2023;2(2):CD010590. Published 2023 Feb 13. doi:10.1002/14651858.CD010590.pub3

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