Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 8, 2018 June 13, 2018, October 29, 2018

MIRCERA® (methoxy polyethylene glycol-epoetin beta)

LENGTH OF AUTHORIZATION: UP TO SIX MONTHS

REVIEW CRITERIA:

INITIAL THERAPY**:**

- Adults diagnosed with anemia due to chronic kidney disease (CKD) not on dialysis or receiving home dialysis; **OR**
- Patients ages 5-17 years of age on hemodialysis who are converting from one erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.
- Trial and failure to one of the preferred medications is required.
- Hemoglobin < 10 g/dL Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
- Lab data within 2 months of PA submission.

CONTINUATION OF THERAPY**:**

- Hemoglobin ≤ 11 g/dL Transferrin saturation ≥ 20% and Serum Ferritin ≥ 100ng/mL.
- Lab data within 2 months of PA submission.

DOSING AND ADMINISTRATION:

Recommended doses for adult patients with CKD not on dialysis:

- If the hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of Mircera, and use the lowest dose of Mircera sufficient to reduce the need for red blood cell transfusions.
- The recommended starting dose is 0.6 mcg/kg once every two weeks intravenously or subcutaneously.
- Once the hemoglobin has been stabilized, Mircera may be administered once monthly using a dose that is twice that of the every-two-week dose and subsequently titrated as necessary.

Recommended doses for adult patients with CKD on dialysis:

- Initiate Mircera treatment when the hemoglobin level is less than 10 g/dL.
- If the hemoglobin level approaches or exceeds 11 g/dL, reduce or interrupt the dose of Mircera.

  - The recommended starting dose of Mircera for the treatment of anemia in adult CKD patients who are not currently treated with an ESA is 0.6 mcg/kg body weight administered as a single IV or SC injection once every two weeks. The IV route is

recommended for patients receiving hemodialysis because the IV route may be less immunogenic.

- Once the hemoglobin has been stabilized, Mircera may be administered once monthly using a dose that is twice that of the every-two-week dose and subsequently titrated as necessary.

Patients ages 5-17 on dialysis:

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

Mircera is not intended for patients who require immediate correction of severe anemia. Mircera may remove the need for maintenance transfusions but is not a substitute for emergency transfusion or treatment of other causes of anemia, such as iron deficiency, underlying infectious, inflammatory, or malignant processes, occult blood loss, underlying hematologic diseases, folic acid, vitamin B-12 deficiency, or hemolysis.