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.*