

SPECIALTY GUIDELINE MANAGEMENT

MIRCERA (methoxy polyethylene glycol-epoetin beta)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Mircera is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in:

- Adult patients on dialysis and adult patients not on dialysis.
- Pediatric patients 5 to 17 years of age on hemodialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.

Limitations of Use:

1. Mircera is not indicated and is not recommended:
 - In the treatment of anemia due to cancer chemotherapy
 - As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia
2. Mircera has not been shown to improve symptoms, physical functioning or health-related quality of life.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Note: Requirements regarding hemoglobin level exclude values due to recent transfusion.

Anemia Due to Chronic Kidney Disease

Authorization of 12 weeks may be granted for the treatment of anemia due to chronic kidney disease when the pretreatment hemoglobin is less than 10 g/dL.

III. CONTINUATION OF THERAPY

Note: Requirements regarding current hemoglobin level exclude values due to recent transfusion.

Anemia Due to Chronic Kidney Disease

1. Authorization of 12 weeks may be granted for continuation of therapy when the current hemoglobin is ≤ 12 g/dL and the member has shown a response to therapy with a rise in hemoglobin of ≥ 1 g/dL after at least 12 weeks of ESA therapy.
2. Authorization of up to 12 weeks may be granted for continuation of therapy in members who have not completed 12 weeks of ESA therapy.

Reference number(s)
1618-A

IV. REFERENCES

1. Mircera [package insert]. South San Francisco, CA: Hoffmann-La Roche Inc.; June 2018.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int.* 2012;Suppl 2:279-335.
3. National Kidney Foundation. KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target. http://www2.kidney.org/professionals/KDOQI/guidelines_anemiaUP/. Accessed September 12, 2017.