

## 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.

###### A. FDA-Approved Indication

Mircera is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis.

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.

###### A. **Anemia Due to CKD**

Authorization of 12 weeks may be granted for the treatment of anemia due to CKD in adult members with pretreatment hemoglobin < 10 g/dL.

##### III. CONTINUATION OF THERAPY

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

###### A. **Anemia Due to CKD**

1. Authorization of 12 weeks may be granted for continuation of therapy in adult members when the current hemoglobin is  $\leq 12$  g/dL and the member has shown a response to therapy with a rise in hemoglobin of  $\geq 1$  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 adult members who have not completed 12 weeks of ESA therapy.

#### IV. REFERENCES

1. Mircera [package insert]. South San Francisco, CA: Hoffmann-La Roche Inc.; April 2016.
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/](http://www2.kidney.org/professionals/KDOQI/guidelines_anemiaUP/). Accessed October 16, 2016.