Clinical Policy: Methoxy polyethylene glycol-epoetin beta (Mircera)

Reference Number: PA.CP.PHAR.238
Effective Date: 01/18
Last Review Date: 04/18 Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established Pennsylvania Health and Wellness®® clinical policy for methoxy polyethylene glycol-epoetin beta (Mircera®).

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

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

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Mircera is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Anemia of Chronic Kidney Disease (must meet all):
1. Diagnosis of anemia associated with chronic kidney disease (CKD) (both dialysis and non-dialysis members);
2. Prescribed by or in consultation with a hematologist or nephrologist;
3. Age ≥ 18 years;
4. ;
5. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%;
6. Pretreatment hemoglobin < 10g/dL;
7. Dosing interval does not exceed once every two weeks.

Approval Duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Anemia of Chronic Kidney Disease (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Hemoglobin is responsive to erythropoiesis-stimulant agent (ESA) therapy;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%;
4. Dosing interval does not exceed once every two weeks.

Approval Duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
   Approval Duration: Duration of request, or 12 weeks (whichever is less);

2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Methoxy polyethylene glycol-epoetin beta is an erythropoiesis-stimulating agent (ESA). It is an erythropoietin receptor activator with greater activity in vivo as well as increased half-life, in contrast to erythropoietin. A primary growth factor for erythroid development, erythropoietin is produced in the kidney and released into the bloodstream in response to hypoxia. In responding to hypoxia, erythropoietin interacts with erythroid progenitor cells to increase red cell production.

Formulations:

- Injection: 50, 75, 100, 150, 200, or 250 mcg in 0.3 mL solution of Mircera in single-use prefilled syringes

Appendices

Appendix A: Abbreviation Key

CKD: chronic kidney disease
ESA: erythropoiesis-stimulating agent

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: removed subjective criteria since specialist requirement is present; changed approval duration from 12 weeks to 6 months; references reviewed and updated.	01.12.18	

References

1. Mircera Prescribing Information. South San Francisco, CA: Genentech USA; August 2015. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed January 12, 2018.