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

Reference Number: PA.CP.PHAR.238
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

Description
Methoxy polyethylene glycol-epoetin beta (Mircera®) is an erythropoiesis-stimulating agent (ESA).

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
- Pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.

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 of CKD and member meets one of the following (a or b):
   a. Age ≥ 18 years (dialysis status is irrelevant);
   b. Age ≥ 5 years, on hemodialysis, and will be converting from another ESA agent (e.g., epoetin alfa, darbepoetin alfa)
2. Prescribed by or in consultation with a hematologist or nephrologist;
3. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100mcg/L or serum transferrin saturation ≥ 20%;
4. Pretreatment hemoglobin < 10g/dL;
5. Dosing interval does not exceed one of the following (a or b):
   a. Adults: SC or IV once every two weeks;
   b. Pediatrics: IV once every four weeks.

Approval Duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

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 one of the following (a or b):
    a. Adults: SC or IV once every two weeks;
    b. Pediatrics: IV once every four 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.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CKD: chronic kidney disease
ESA: erythropoiesis-stimulating agent
FDA: Food and Drug Administration
RBC: red blood cell

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
    - Uncontrolled hypertension
    - Pure red cell aplasia (PRCA) that begins after treatment with erythropoietin protein drugs
    - Allergic reactions, anaphylaxis
- Boxed warning(s): ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Anemia due to CKD	**Adult patients with CKD on or not on dialysis** Initial treatment: 0.6 mcg/kg body weight SC or IV once every two weeks Maintenance treatment: dose twice that of the every-two-week dose SC or IV once monthly Conversion from another ESA: dosed SC or IV once monthly or once every two weeks based on total weekly epoetin alfa or darbepoetin alfa dose at time of conversion **Pediatric patients with CKD on hemodialysis** Conversion from another ESA: dosed IV once every four weeks based on total weekly epoetin alfa or darbepoetin alfa dose at time of conversion.	Varies

V. Product Availability

Injection (single-dose prefilled syringe): 30, 50, 75, 100, 120, 150, 200, or 250 mcg in 0.3 mL solution; 360 mcg in 0.6 mL solution

VI. References

1. Mircera Prescribing Information. South San Francisco, CA: Genentech USA; June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125164s078lbl.pdf. Accessed January 30, 2019.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0887	Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)
J0888	Injection, epoetin beta, 1 microgram, (for Non ESRD use)

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	
2Q 2019 annual review: age extension for a current P & T approved use (criteria added to allow treatment of anemia in pediatric patients with CKD age 5 to 17 years of age on hemodialysis who are converting from another ESA per labeling changes); added new 360 mcg/0.6 mL dosage strength; references reviewed and updated.	04/19	