Clinical Policy: Methoxy Polyethylene Glycol-epoetin Beta (Mircera)

Reference Number: IL.ERX.SPA.323
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 is not indicated and is not recommended for use:
  - 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.
- Mircera has not been shown to improve symptoms, physical functioning or health-related quality of life.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Mircera is **medically necessary** when 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 to ≤ 17 years, on dialysis, 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 ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
4. Pretreatment hemoglobin < 10 g/dL;
5. Failure of Epogen® or Procrit® unless contraindicated or clinically significant adverse effects are experienced;
6. 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
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Anemia of Chronic Kidney Disease (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Failure of Epogen or Procrit unless contraindicated or clinically significant adverse effects are experienced;
4. Adequate iron stores as indicated by current (within the last 3 months) serum ferritin level ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
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 (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Anemia due to cancer chemotherapy;

B. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. 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

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Epogen®, Procrit® (epoetin alfa)	**Anemia due to CKD** Initial dose: 50 to 100 units/kg 3 times weekly (adults) intravenously (IV) or subcutaneously (SC) and 50 units/kg 3 times weekly (children on dialysis) IV or SC. Individualize maintenance dose. IV route recommended for patients on hemodialysis.	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

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

Appendix D: General Information

- The 2012 Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Anemia in Chronic Kidney Disease state that there is no evidence that any given ESA brand is superior to another in terms of patient outcomes. It is considered opinion of the Work Group that the likelihood of differences in clinical outcomes among ESA brands is low. The guideline recommends choosing an ESA based on the balance of pharmacodynamics, safety information, clinical outcome data, costs, and availability (Level 1, Grade D recommendation).

V. 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

VI. 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

VII. 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 February 22, 2021.
2. Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Official Journal of the International Society of Nephrology – Kidney International Supplements August 2012. 2(4): 279-335.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.19.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.