RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	methoxy polyethylene glycol-epoetin beta
Policy Number:	RxA.208
Drug(s) Applied:	Mircera®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Methoxy polyethylene glycol-epoetin beta (Mircera)	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	Varies

		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.	

Dosage Forms

- 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

Clinical Policy

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

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 Procrit®, unless contraindicated or clinically significant adverse effects are experienced;
   *Prior authorization is required for Procrit
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

Medicaid: 6 months

Commercial: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
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. 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
Medicaid: 6 months
Commercial: 6 months

III. Appendices

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
Procrit (epoetin alfa)	**Anemia due to CKD** Adults: 50-100 Units/kg IV or SC TIW Pediatrics (age 1 month or older): 50 Units/kg IV or SC TIW	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

None

References

1. Mircera Prescribing Information. South San Francisco, CA: Genentech USA; August 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125164s078lbl.pdf. Accessed June 22, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed 1. Reformatted age “Age 5 to 17 years” 2. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 3. Initial Therapy criteria & Continued Therapy criteria: Added Approval Duration Medicaid: 6 months; Updated Approval duration for commercial to 6 months 4. Reference reviewed and updated.	06/22/2020	09/14/2020