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

Reference Number: CP.PHAR.238
Effective Date: 06.01.16
Last Review Date: 08.18 Coding Implications
Line of Business: HIM, 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:
  - 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.
- 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.

It is the policy of health plans affiliated with Centene Corporation® 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 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 ≥ 100 mcg/L or serum transferrin saturation ≥ 20%;
4. Pretreatment hemoglobin < 10 g/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

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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: 6 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid 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

Not applicable

Appendix C: Contraindications

- Uncontrolled hypertension
- Black box warnings:
  - CKD:
    - In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL
    - No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.
    - Use of the lowest Mircera dose sufficient to reduce the need for RBC transfusions is recommended.
  - Cancer:
    - Mircera is not indicated and is not recommended for treatment of anemia due to cancer chemotherapy. A dose-ranging study of Mircera was terminated early due to more deaths among patients receiving Mircera than another ESA.
    - ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.

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 administered SC or IV once every two weeks Maintenance treatment: dose twice that of the every-two-week dose administered 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-use prefilled syringe): 50, 75, 100, 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 July 5, 2018.

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	P&T Approval Date
Policy developed.	05.16	06.16
Removed requirement related to failure of, or contraindication or intolerance to Epogen.	09.16	
Initial: added prescriber specialty; modified requirement related to adequate iron stores by requiring current (within the last 3 months) serum ferritin or serum transferrin saturation lab values; added dosing interval does not exceed once every 2 weeks per PI (and on re-auth); re-auth: modified requirement related to hemoglobin level to allow reduction in dose per PI; updated references.	05.17	06.17
2Q 2018 annual review: policies combined for Medicaid and HIM line of business; removed subjective criteria since specialist requirement is present; changed approval duration from 12 weeks to 6 months; references reviewed and updated.	01.12.18	05.18
No significant changes: 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.	07.16.18	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.