Clinical Policy: Methoxy polyethylene glycol-epoetin beta (Mircera)
Reference Number: CP.CPA.322
Effective Date: 06.01.18
Last Review Date: 05.19
Line of Business: Commercial

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:
  o In the treatment of anemia due to cancer chemotherapy
  o 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.

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 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: 6 months or to member's renewal period, whichever is longer**

B. **Other diagnoses/indications**  
1. Refer to CP.CPA.09 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 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 or to the member’s renewal date, whichever is longer**

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 CP.CPA.09 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 – CP.CPA.09 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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procrit (epoetin alfa)</td>
<td><strong>Anemia due to CKD</strong></td>
<td>Varies</td>
</tr>
<tr>
<td>Adults:</td>
<td>50-100 Units/kg IV or SC TIW</td>
<td></td>
</tr>
<tr>
<td>Pediatrics (age 1 month or older):</td>
<td>50 Units/kg IV or SC TIW</td>
<td></td>
</tr>
</tbody>
</table>

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

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia due to CKD</td>
<td><strong>Adult patients with CKD on or not on dialysis</strong></td>
<td>Varies</td>
</tr>
<tr>
<td>Initial treatment: 0.6 mcg/kg body weight SC or IV once every two weeks</td>
<td></td>
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<tr>
<td>Maintenance treatment: dose twice that of the every-two-week dose SC or IV once monthly</td>
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</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pediatric patients with CKD on hemodialysis</strong></td>
<td><strong>Conversion from another ESA: dosed IV once every four weeks based on total weekly</strong></td>
<td></td>
</tr>
</tbody>
</table>
**Indication**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td></td>
<td>epoetin alfa or darbepoetin alfa dose at time of conversion.</td>
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</table>

**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**


**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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>J0887</td>
<td>Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)</td>
</tr>
<tr>
<td>J0888</td>
<td>Injection, epoetin beta, 1 microgram, (for Non ESRD use)</td>
</tr>
</tbody>
</table>

**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
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<tbody>
<tr>
<td>01.16.18</td>
<td>05.18</td>
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New policy created: split from CP.CPA.75 Hematopoietic Agents (Aranesp, Epogen, Mircera, Procrit); added criteria related to prescriber, age, adequate iron stores, pretreatment hemoglobin level, and dose; Re-auth: removed requirement related to dosage reduction per hemoglobin level since it is not a hard stop to discontinue and specialist is involved in care; references reviewed and updated.

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.

2Q 2019 annual review: No significant changes; references reviewed and updated.

**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.
CLINICAL POLICY
Methoxy Polyethylene Glycol-Epoetin Beta

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.

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