Mircera® (methoxy polyethylene glycol-epoetin beta)  
(Intravenous/Subcutaneous)  

*NON-DIALYSIS*  

Document Number: IC-0244  

Last Review Date: 09/01/2020  
Date of Origin: 01/06/2015  

I. Length of Authorization
   • Coverage will be provided for 45 days and may be renewed.

II. Dosing Limits
   A. Quantity Limit (max daily dose) [NDC Unit]:
      - 30 mcg; 50 mcg; 75 mcg; 100 mcg; 120 mcg; 150 mcg: 1 pre-filled syringe every 14 days
      - 200 mcg; 250 mcg; 360 mcg: 1 pre-filled syringe every 28 days
   B. Max Units (per dose and over time) [HCPCS Unit]:
      • 360 billable units every 28 days

III. Initial Approval Criteria

Coverage is provided in the following condition(s):
   • Patient must be 18 years or older: AND

Universal Criteria:
   • Lab values are obtained within 30 days of the date of administration (unless otherwise indicated): AND
   • Patient has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*: AND
   • Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out: AND
   • Patient does not have uncontrolled hypertension: AND

Anemia secondary to chronic kidney disease (non-dialysis patients) †
   • Initiation of therapy Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%
IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal criteria indentified in section III: AND
- Previous dose was administered within the past 60 days: AND
- Anemia response compared to pretreatment baseline: AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, Stevens-Johnson syndrome/toxic epidermal necrolysis, etc.), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, uncontrolled hypertension), seizures, etc.: AND
- Hemoglobin (Hb) <11 g/dL and/or Hematocrit (Hct) <33%; AND

* Intravenous iron supplementation may be taken into account when evaluating iron status

- Functional iron deficiency (i.e., adequate iron stores with an insufficient supply of available iron) may occur in patients with chronic diseases, cancer, and/or in those currently receiving ESAs.
- Iron is not generally recommended in anemic patients with a Ferritin >500 ng/mL
- Anemic patients with a Ferritin <500 ng/mL AND TSAT <50% may derive benefit from IV iron therapy in conjunction with ESA

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults with CKD</td>
<td>Starting dose: 0.6 mcg/kg IV or SC once every 2 weeks</td>
</tr>
<tr>
<td>– Non-dialysis</td>
<td>Maintenance dose: Once monthly dosing (at twice the every-two-week dose) may occur once Hb has been stabilized. Most commonly the dose ranges from 120 to 360 mcg every 4 weeks.</td>
</tr>
</tbody>
</table>

- Dose increases of 25% can be considered if after 4 weeks of initial therapy the hemoglobin has increased less than 1 g/dL and the current hemoglobin level is less than the indication specific level noted above
- Dose decreases of 25% or more can be considered if the hemoglobin rises rapidly by more than 1 g/dL in any 2-week period
- Avoid frequent dose adjustments. Do not increase the dose more frequently than once every 4 weeks; decreases can occur more frequently.
- Dose and frequency requested are the minimum necessary for the patient to avoid RBC transfusions. If patients fail to respond over a 12-week dose escalation period, further dose increases are unlikely to improve response and discontinuation of therapy should be considered.

VI. Billing Code/Availability Information

HCPCS:

- J0888 – Injection, epoetin beta, 1 microgram, (for non esrd use): 1 billable unit = 1 mcg
NDC:

- Mircera 30 mcg/0.3 mL single-dose prefilled syringe: 59353-0400-xx
- Mircera 50 mcg/0.3 mL single-dose prefilled syringe: 59353-0401-xx
- Mircera 75 mcg/0.3 mL single-dose prefilled syringe: 59353-0402-xx
- Mircera 100 mcg/0.3 mL single-dose prefilled syringe: 59353-0403-xx
- Mircera 120 mcg/0.3 mL single-dose prefilled syringe: 59353-0407-xx
- Mircera 150 mcg/0.3 mL single-dose prefilled syringe: 59353-0404-xx
- Mircera 200 mcg/0.3 mL single-dose prefilled syringe: 59353-0405-xx
- Mircera 250 mcg/0.3 mL single-dose prefilled syringe: 59353-0406-xx
- Mircera 360 mcg/0.6 mL single-dose prefilled syringe: 59353-0408-xx

VII. References

Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>D63.1</td>
<td>Anemia in chronic kidney disease</td>
</tr>
<tr>
<td>I12.9</td>
<td>Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease</td>
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<tr>
<td>I13.0</td>
<td>Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease</td>
</tr>
<tr>
<td>I13.10</td>
<td>Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease</td>
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<tr>
<td>N18.30</td>
<td>Chronic kidney disease, stage 3 (moderate), unspecified</td>
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<tr>
<td>N18.31</td>
<td>Chronic kidney disease, stage 3a</td>
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<tr>
<td>N18.32</td>
<td>Chronic kidney disease, stage 3b</td>
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<tr>
<td>N18.4</td>
<td>Chronic kidney disease, stage 4 (severe)</td>
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<tr>
<td>N18.9</td>
<td>Chronic kidney disease, unspecified</td>
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</table>

Dual coding requirements:
- Anemia due to CKD (not on dialysis): must bill D63.1 AND I12.9, I13.0, I13.10, N18.3, N18.4, or N18.9

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

<table>
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<th>5, 8</th>
<th>NCD/LCD Document (s):</th>
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MIRCERA (methoxy polyethylene glycol-epoetin beta)
Non-Dialysis Prior Authorization Criteria

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<tr>
<th>Jurisdiction</th>
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<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
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<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
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</tr>
<tr>
<td>N (9)</td>
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<td>First Coast Service Options, Inc.</td>
</tr>
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<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto GBA, LLC</td>
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<tr>
<td>M (11)</td>
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</tr>
<tr>
<td>K (13 &amp; 14)</td>
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<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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Jurisdiction(s): 15
NCD/LCD Document(s): L34356


Jurisdiction(s): 5, 8
NCD/LCD Document(s): A56795


Jurisdiction(s): N
NCD/LCD Document(s): A57628


Jurisdiction(s): 15
NCD/LCD Document(s): A56462