Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

RETIRED

Effective Date: 06/10/2021

Mircera® (methoxy polyethylene glycol-epoetin beta)

FDA approval: November 2007
HCPCS: J0887, J0888
Benefit: Medical & Pharmacy

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Adults
      i. A diagnosis of anemia associated with CKD in adult patients on dialysis and not on dialysis
      ii. Patient's hemoglobin must be less than 10 g/dL prior to initiation of therapy
      iii. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list and/or BCBSM/BCN prior authorization and step therapy documents
   b. Children 5 – 17 years
      i. Currently receiving hemodialysis
      ii. Converting from another erythropoiesis stimulating agents (ESA) after hemoglobin was stable with another ESA

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Initial Authorization Period: 3 months
   b. Renewal Criteria:
      i. Dose adjustments are required to maintain hemoglobin between 10 - 11.5 g/dL
      ii. Dose adjustments are required to maintain hemoglobin between 11 - 12 g/dL in children 5-17
   c. Renewal Authorization Period:
      i. 3 months
      ii. Coverage may be reviewed annually thereafter

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. **FDA approved indication /Diagnosis**

**Please refer to most recent prescribing information.*

B. **Background Information**

a. Red blood cell production is controlled by the hormone erythropoietin (EPO), which is produced in the kidney in response to hypoxia
b. In adults, EPO is mainly produced by the kidney
c. Patients with CKD gradually develop an inability to produce adequate EPO to maintain normal hemoglobin concentration
d. Anemia is observed as early as stage 3 CKD and is almost universal by stage 4
e. A normocytic, normochromic anemia is observed due to insufficient production of erythropoietin by the diseased kidneys
f. Patients with anemia secondary to chronic kidney disease are ideal candidates for epoetin therapy because the disorder represents a pure erythropoietin deficiency state
g. Epoetin alfa (Epogen, Procrit), darbepoetin alfa (Aranesp), and methoxy polyethylene glycol-epoetin beta (Mircera) are available in the United States for the treatment of anemia associated with CKD
h. These agents are erythropoietin analogs that activate the EPO receptor and stimulate erythropoiesis
i. The most recent guidelines for the treatment of anemia of CKD are available from KDIGO (2012)
j. Anemia is defined as Hb < 13.0 g/dl in males and < 12.0 g/dl in females greater than 15 year of age
k. For children, anemia is defined as Hb < 11.g g/dl (0.5-5 years), < 11.5 g/dl (5-12 years), and < 12.0 g/dl (12-15 years)
l. Correction of iron deficiency, an important cause of hyporesponsiveness to ESA treatment, in appropriate patients can reduce the severity of anemia and improve the erythropoietic response to ESA treatment
m. All correctable causes should be treated before considering ESA therapy
n. The recommendation from the Work Group is treatment of Hb less than 10 g/dl to avoid a drop below 9 g/dl that is associated with a higher risk of transfusions
o. For CKD patients not on dialysis, treatment of Hb <10.0 g/dl may be appropriate
p. ESAs should not be used to maintain Hb concentration > 11.5 g/dl in adult patients due to increased risk of cardiovascular events
q. Pediatric CKD patients should be treated to a Hb in the range of 11.0 to 12.0 g/dl

C. **Efficacy**

**Please refer to most recent prescribing information.*

D. **Medication Safety Considerations**

**Please refer to most recent prescribing information.*

E. **Dosing and administration**

**Please refer to most recent prescribing information.*

F. **How supplied**

**Please refer to most recent prescribing information.*

References:

1. Macdougall I, Ashenden M. Current and Upcoming Erythropoiesis-Stimulating Agents, Iron Products, and Other Novel Anemia Medications. *ACKD*.2009;16(2):117-130.
2. Bargman J, Skorecki K. Chapter 280. Chronic Kidney Disease. *Harrison's Principles of Internal Medicine.* 18th ed. New York, NY: McGraw-Hill;2012.
3. Kaushansky K, Kipps T. Chapter 37. Hematopoietic Agents: Growth Factors, Minerals, and Vitamins. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 12th ed. New York: McGraw-Hill; 2011.
4. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int.* 2012;2(4):1-64.
5. Macdougall I, Walker R, Provenzano R, et al. C.E.R.A Corrects Anemia in Patients with Chronic Kidney Disease not on Dialysis: Results of a Randomized Clinical Trial. *Clin J Am Soc Nephrol.* 2008;3(2):337-347.
6. Klinger M, Arias M, Vargemezis V, et al. Efficacy of intravenous methoxy polyethylene glycol-epoetin beta administered every 2 weeks compared with epoetin administered 3 times weekly in patients treated by hemodialysis or peritoneal dialysis: a randomized trial. *Am J Kidney Dis*. 2007;50(6):989-1000.
7. Mircera® (methoxy polyethylene glycol-epoetin beta) [prescribing information].South San Francisco, CA: Hoffman-La Roche Inc.; 6/2018.
8. Fischbach M, Wuhl E, Reigner SCM et al. Efficacy and Long-Term Safety of C.E.R.A. Maintenance in Pediatric Hemodialysis Patients with Anemia of CKD CJSAN Jan 2018, 13 (1) 81-90.

<table>
<tr><td colspan="3">Policy History</td></tr>
<tr><td>#</td><td>Date</td><td>Change Description</td></tr>
<tr><td>1.5</td><td>Effective Date: 06/10/2021</td><td>Policy to be retired as Mircera criteria is also housed in the ESA policy which is only active for the Medicare line of business</td></tr>
<tr><td>1.4</td><td>Effective Date: 11/07/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.3</td><td>Effective Date: 11/01/2018</td><td>Update with pediatric indication</td></tr>
<tr><td>1.2</td><td>Effective Date: 11/09/2017</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.1</td><td>Effective Date: 11/10/2016</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.0</td><td>Effective Date: 05/07/2015</td><td>New Policy
<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*