

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Mircera (methoxy polyethylene glycol-epoetin beta)

Override(s)	Approval Duration
Prior Authorization	6 months

Medications
Mircera (methoxy polyethylene glycol-epoetin beta)

### APPROVAL CRITERIA

Requests for Mircera (methoxy polyethylene glycol-epoetin beta) may be approved if the following criteria are met:

- I. Individual has a baseline hemoglobin (Hgb) level less than 10 g/dL; **AND**
- II. Baseline iron status is adequate as defined by one of the following:
  - A. Transferrin saturation is at least 20%; **OR**
  - B. Ferritin is at least 80 ng/mL; **OR**
  - C. Bone marrow demonstrates adequate iron stores;

#### **AND**

- III. Individual is using for one of the following:
  - A. Anemia associate with chronic kidney disease (CKD), for individuals on dialysis, to achieve and maintain Hgb levels within the range of 10 to 11 g/dL; **OR**
  - B. Anemia associated with CKD, for individuals **not** on dialysis, to achieve and maintain hemoglobin levels of 10 g/dL.

Requests for Mircera (methoxy polyethylene glycol-epoetin beta) may **not** be approved for the following:

- I. Continued use when the hemoglobin level exceeds 11 g/dL unless otherwise specified; **OR**
- II. Individual with uncontrolled hypertension; **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- III. Use beyond 12 weeks in the absence of response in individuals with chronic kidney disease; **OR**
- IV. As treatment in the presence of a sudden loss of response with severe anemia and a low reticulocyte count.

**Note:** Erythropoiesis-stimulating agents (ESAs) have black box warnings for an increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence.

For CKD: In controlled trials, individuals experienced greater risks for death, serious adverse cardiovascular reactions and stroke when ESAs were administered to target a Hgb level greater than 11 g/dL. Use the lowest dose needed to reduce the need for red blood cell (RBC) transfusions.

For Cancer: In controlled trials, ESAs shortened overall survival and/or increased the risk for tumor progression or recurrence in individuals with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers. Use the lowest dose needed to avoid RBC transfusions. Use ESAs only for anemia from myelosuppressive chemotherapy when the anticipated outcome is not cure and discontinue ESAs following completion of a chemotherapy course.

For Perisurgery: Deep venous thrombosis (DVT) prophylaxis is recommended due to increased risk for DVTs.

ESAs are contraindicated in individuals with uncontrolled hypertension. Blood pressure should be adequately controlled prior to initiation and during treatment with ESAs.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 20, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2016 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: July 13, 2018.
6. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Inter.* 2012; Suppl 2: 279–335. Available from: [https://www.kidney.org/professionals/guidelines/guidelines\\_commentaries/anemia](https://www.kidney.org/professionals/guidelines/guidelines_commentaries/anemia). Accessed on: July 13, 2018.

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7. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) 2017 National Comprehensive Cancer Network, Inc. Cancer- and Chemotherapy-Induced Anemia. Version 1.2018. Available at: NCCN.org. Updated periodically. Accessed on: July 20, 2018.

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