

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

*FHK- Florida Healthy Kids

Mircera (methoxy polyethylene glycol-epoetin beta) CG-DRUG-05

Override(s)	Approval Duration
Prior Authorization	Initial Therapy: 12 weeks Continuation Therapy: 12 weeks

Medications
Mircera (methoxy polyethylene glycol-epoetin beta)

APPROVAL CRITERIA

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

- I. The individual has a hemoglobin (Hgb) level less than 10 g/dL prior to initiation of therapy; **AND**
- II. Prior to initiation of therapy, evaluation of the individual's iron status reveals:
 - 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. For individuals with hypertension, blood pressure is adequately controlled before *initiation* of therapy and closely monitored and controlled during therapy; **AND**
- IV. The individual has anemia associated with chronic kidney disease (CKD) and meets one of the following:
 - A. Individual is on dialysis and the goal is to achieve and maintain hemoglobin levels within the range of 10.0 to 11.0 g/dL; **OR**
 - B. Individual is **not** on dialysis and the goal is to achieve and maintain hemoglobin levels of 10.0 g/dL.

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

- I. When the above criteria are not met;
- II. Continued use when the hemoglobin level exceeds 11.0 g/dL (except when the dose of methoxy polyethylene glycol-epoetin beta is adjusted to achieve and maintain target hemoglobin not to exceed 11.0 g/dL);
- III. Use beyond 12 weeks in the absence of response in individuals with chronic kidney disease;
- IV. To treat anemia in individuals due to other factors such as cancer chemotherapy, iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic diseases (such as sickle cell anemia, thalassemia, and porphyria);
- V. As treatment in the presence of a sudden loss of response with severe anemia and a low reticulocyte count.

Note: Mircera (methoxy polyethylene glycol-epoetin beta) has black box warnings for increased mortality, serious cardiovascular and thromboembolic events, and tumor progression. Individuals in renal failure experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels in clinical trials. Dosing should be individualized to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL. Mircera is not indicated for the treatment of anemia due to cancer chemotherapy.

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

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 3, 2018.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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.