methoxy polyethylene glycol-epoetin beta (Mircera)

Commercial Medical Benefit Drug Policy

For oncology-related indications, medical necessity criteria can be found here: Blue Shield Oncology-Related Medication Policies.

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's CarePro Provider Portal to submit your request.

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration
Self-Administration

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: Long-acting erythropoiesis-stimulating agent (ESA)
HCPCS:
J0888:Injection, epoetin beta, 1 microgram, (for non esrd use)
How Supplied:
30 mcg, 50 mcg, 75 mcg, 100 mcg, 120 mcg, 150 mcg, 200 mcg (in 0.3 mL solution in single-dose prefilled syringes)

Condition(s) listed in policy *(see coverage criteria for details)*

- Anemia Due to Chronic Renal Failure

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Aranesp, Epogen, Procrit, and Retacrit are the BSC preferred erythropoiesis stimulating agent (ESA). For all indications, intolerance, or contraindication to two of these preferred drugs is required for members newly initiating ESA therapy.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Anemia Due to Chronic Renal Failure

Meets medical necessity if all the following are met:

1. Intolerance or contraindication with two preferred products (Aranesp, Epogen, Procrit, or Retacrit) that is not expected with Mircera
2. Patient is not on hemodialysis(if patient is on hemodialysis or peritoneal dialysis, the dialysis center is responsible for supplying and administering the drug)
3. Hemoglobin is less than 10 g/dl
4. Both Primary and Secondary ICD-10 codes must be met

Covered Doses:

Up to 180 mcg IV/SC once every two weeks or 360 mcg IV/SC once monthly

Coverage Period:

Initial: 1 year

Reauthorization: Cover yearly if meets all the following below

1. Patient is not on hemodialysis(if patient is on hemodialysis or peritoneal dialysis, the dialysis center is responsible for supplying and administering the drug)
2. Not on hemodialysis
3. Hgb ≤ 11 g/dL

ICD-10:

Primary: D63.1 (Anemia in chronic kidney disease)
Secondary: N18.1-N18.9 (CRF)

References

1. AHFS. Available by subscription at http://www.lexi.com
   DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2:279–335.
3. Mircera (methoxy polyethylene glycol-epoetin beta) Prescribing Information. Vifor (International) Inc., Gallen, Switzerland: 6/2024.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- For oncology-related indications, medical necessity criteria can be found here: Blue Shield Oncology-Related Medication Policies.
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