

methoxy polyethylene glycol-epoetin beta (Mircera)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

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, or 250 mcg (in 0.3 mL solution in single-dose prefilled syringes)
- 360 mcg (in 0.6 mL solution in single-dose prefilled syringes)

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

- Anemia Due to Chronic Renal Failure

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

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.

For members enrolled in our Blue Shield Select (PPO) and Blue Shield Medicare (PPO) plans:

Mircera requires step therapy. Step therapy requires you to try other drugs first before another drug can be covered. The BSC preferred step drugs are Aranesp, Epogen, Procrit, and Retacrit. Two of these drugs will need to be tried first for members newly initiating Mircera 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:

Blue Shield of California is an independent member of the Blue Shield Association

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Effective: 12/01/2024

Y0118_24_675A1_C 10162024

H2819_24_675A1_C Accepted 10212024

INITIAL:

1. NOT on hemodialysis
2. Hemoglobin is less than 10 g/dl
3. **For PPO request:** Intolerance or contraindication with two preferred products (Aranesp, Epogen, Procrit, or Retacrit) that is not expected with Mircera

REAUTHORIZATION:

1. Not on hemodialysis
2. Hgb is 11 g/dL or less

Covered Doses:

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

Coverage Period:

Initial: 1 year

Reauthorization: Yearly

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Mircera
2. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer’s prescribing information.
- Support for using erythropoiesis-stimulating agents (ESAs) for anemia of chronic renal failure is found in the 2012 KDIGO 2012 Clinical Practice Guideline for Anemia in Chronic Kidney Disease (CKD). The KDIGO practice guideline supports the use of ESAs for treatment of anemia in CKD patients with hemoglobin <10.0 g/dL.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at <https://www.cms.gov/Medicare-Coverage-Database/search.aspx>
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at <http://www.lexi.com>
DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
5. 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.
6. Mircera (methoxy polyethylene glycol-epoetin beta) Prescribing Information. Vifor (International) Inc., Gallen, Switzerland, 6/2024.

Review History

Date of Last Annual Review: 1Q2024

Changes from previous policy version:

methoxy polyethylene glycol-epoetin beta (Mircera)

Effective: 12/01/2024

- New Part B policy

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*

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