Methoxy polyethylene glycol-epoetin beta (Mircera®)	Place of Service Office Administration Outpatient Facility Administration Infusion Center Administration Home Infusion Administration Self-Administration HCPCS: J0888 per 1 mcg (non-ESRD)

Condition listed in policy *(see criteria for details):*

- Anemia due to chronic renal failure (CRF)

AHFS therapeutic class: Hematopoietic Agent

Mechanism of action: Long-acting erythropoiesis-stimulating agent (ESA)

(1) Special Instructions and Pertinent Information

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

Retacrit is the BSC preferred erythropoiesis stimulating agent (ESA). For all indications, treatment failure, intolerance or contraindication to Retacrit (epoetin alfa-epbx) is required for members newly initiating ESA therapy.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Mircera® (methoxy polyethylene glycol-epoetin beta) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Anemia due to chronic renal failure

1. **Patient has failed, is intolerant to, or is contraindicated to Retacrit** as defined by any one of the following:
    a. At the max dose of Retacrit for 8 weeks, patient does not meet Hgb target, or Hgb does not rise by at least 2g/dL
    b. Patient has a contraindication to Retacrit that is not also a contraindication of Mircera
    c. Patient has known side effects to Retacrit that would not be expected with Mircera
    d. Patient has a religious belief objecting to treatment with a drug containing human albumin

    AND
2. Hemoglobin is less than 10 g/dl, **AND**
3. Both Primary and Secondary ICD-10 codes must be met

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: Cover yearly if Hgb ≤ 11 g/dL

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

ICD-10:
Primary: D63.1 (Anemia in chronic kidney disease)
Secondary: N18.1-N18.9 (CRF)

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Mircera® (methoxy polyethylene glycol-epoetin beta) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Treatment is not covered when Hgb > 12 g/dL or HCT > 36% for all indications
- (280.0) Iron deficiency anemias; secondary to blood loss (chronic)
- (280.9) Iron deficiency anemia, unspecified
- (281.9) Unspecified deficiency anemia
- (283.0) Autoimmune hemolytic anemias
- (284.9) Aplastic anemia, unspecified
- (285.9) Anemia, unspecified
- (288.0) Agranulocytosis
- (289.9) Unspecified diseases of blood and blood forming organs
- (451.9) Phlebitis and thrombophlebitis; of deep vessels of lower extremities; other
- (V59.01) Donors; blood; whole blood
- (205.00-205.91) Myeloid leukemia
- (206.00-206.91) Monocytic leukemia

- (207.00-208.91) Other specified and unspecified leukemias

Anemias due to:

- Athletic performance management
- Beta-thalassemia
- Blood transfusion reduction
- Cancer radiotherapy
- Cofactor deficiencies
- Congestive heart failure
- Folate deficiency anemia
- Hemolysis
- Hemorrhage
- HIV Treatment
- Insulin resistance
- Most patients with GI bleeding
- Nutritional deficiencies
- Porphyria
- Postpartum
- Pre-operative prevention in anemic patients
- Prematurity
- Refractory anemia such as thalassemia or sickle cell disease
- Rheumatoid arthritis
- Ribavirin therapy
- Sexual dysfunction
- Sickle-cell anemia
- Transfusional iron overload
- Untreated underlying infections

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

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)

Dose conversion from current ESA to Mircera (from Mircera prescribing information).

Previous Epoetin alfa (units/week)	Previous Darbepoetin alfa (mcg/week)	Mircera Dose	
		Once Monthly	Once q 2 Weeks
< 8000	< 40	120 mcg	60 mcg
8000 - 16000	40 - 80	200 mcg	100 mcg
> 16000	> 80	360 mcg	180 mcg

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

- Mircera (methoxy polyethylene glycol-epoetin beta) [Prescribing information]. Gallen, Switzerland: Vifor (International) Inc.; 03/2023.

(7) Policy Update

Date of last revision: 4Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee