POLICY Document for MIRCERA (methoxy polyethylene glycol-epoetin beta)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
ERYTHROPOIESIS STIMULATING AGENTS
PREFERRED PRODUCTS: ARANESP, RETACRIT, PROCRIT

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the erythropoiesis stimulating agents specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members who are requesting treatment with the targeted products.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Erythropoiesis stimulating agents

	Product(s)
Preferred*	• **Aranesp** (darbepoetin alfa) • **Procrit** (epoetin alfa) • **Retacrit** (epoetin alfa-epbx)
Targeted	• **Epogen** (epoetin alfa) • **Mircera** (methoxy polyethylene glycol-epoetin beta)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

A. Mircera

1. The request is for anemia due to chronic kidney disease

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2. Coverage for the targeted product is provided when the member has a documented inadequate response or intolerable adverse event with all of the preferred products.

B. Epogen

Coverage for the targeted products are provided when both of the following criteria are met:

1. Member has had a documented intolerable adverse event with the preferred product, Retacrit and Procrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
2. Member has experienced a documented inadequate response or intolerable adverse event with the preferred product, Aranesp, when prescribed for the treatment of anemia due to chronic kidney disease or the treatment of anemia due to myelosuppressive chemotherapy in cancer.

Section 2: Clinical Criteria

Specialty Guideline Management Mircera

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Mircera	methoxy polyethylene glycol-epoetin beta

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Mircera is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in:

- Adult patients on dialysis and adult patients not on dialysis.
- Pediatric patients 3 months to 17 years of age on dialysis or not on dialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.

All other indications are considered experimental/investigational and not medically necessary.

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Coverage Criteria

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before starting Mircera. Members may not use Mircera concomitantly with other erythropoiesis stimulating agents.

Anemia Due to Chronic Kidney Disease (CKD)[1,2]

Authorization of 12 weeks may be granted for the treatment of anemia due to CKD in adult members with pretreatment hemoglobin less than 10 grams per deciliter (g/dL).

Authorization of 12 weeks may be granted for the treatment of anemia due to CKD in pediatric members 3 months to 17 years of age who are converting from another ESA after their hemoglobin level was stabilized (e.g., Hgb level of 10 to 12 g/dL) with an ESA.

Continuation Of Therapy

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% with the prior 3 months) or are receiving iron therapy before continuation of treatment with Mircera. Members may not use Mircera concomitantly with other erythropoiesis-stimulating agents.

All members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of Mircera treatment must show a response with a rise in hemoglobin of greater than or equal to 1 g/dL. Members who have completed less than 12 weeks of Mircera treatment and have not yet responded with a rise in hemoglobin of greater than or equal to 1 g/dL may be granted authorization of up to 12 weeks to allow for sufficient time to demonstrate a response.

Anemia Due to Chronic Kidney Disease (CKD)[1,2]

Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in members with current hemoglobin less than 12 g/dL.

REFERENCES:

SECTION 1

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
3. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; June 2024.
4. Procrit [package insert]. Horsham, PA: Janssen Products, LP; July 2018.

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5. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2024.

SECTION 2

1. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; April 2024.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012;Suppl 2:279-335.

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