CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Erythropoiesis-Stimulating Agents – Mircera Utilization Management Medical Policy
- Mircera® (methoxy polyethylene glycol-epoetin beta intravenous or subcutaneous injection – Vifor)

REVIEW DATE: 06/17/2026

OVERVIEW

Mircera, an erythropoiesis-stimulating agent (ESA), is indicated for the treatment of **anemia due to chronic kidney disease** (CKD) in:[1]
- Adults on dialysis and adults not on dialysis.
- Pediatric patients 3 months to 17 years of age on dialysis or not on dialysis who are converting from another ESA after their hemoglobin (Hb) level was stabilized with an ESA.

Limitations of Use: Mircera has not been shown to improve quality of life, fatigue, or patient well-being.[1] Mircera is not indicated and not recommended for the following uses:
- Treatment of anemia due to cancer chemotherapy.
- As a substitute for red blood cell (RBC) transfusions in those who require immediate correction of anemia.

The iron status should be evaluated in all patients before and during treatment with ESAs.[1] Therapy should be initiated for **adults with CKD on dialysis** when the Hb level is < 10.0 g/dL. If the Hb level approaches or exceeds 11.0 g/dL, reduce or interrupt the dose of Mircera. For **adults with CKD who are not on dialysis**, consider initiating Mircera only when the Hb is < 10.0 g/dL and other considerations apply (e.g., rate of Hb decline indicates patient is likely to need RBC transfusion and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal). If the Hb exceeds 10.0 g/dL, reduce or interrupt the Mircera dose and use the lowest dose sufficient to reduce the need for RBC transfusions. Therapy with Mircera for **pediatric patients with CKD** should only be initiated when the Hb level has already been stabilized by treatment with an ESA (conversion therapy). If the Hb level approaches or exceeds 12.0 g/dL, reduce or interrupt the dose of Mircera.

Guidelines

The Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for anemia in CKD (2026) provide recommendations for the use of ESAs.[2] Guidelines recommend addressing all correctable causes of anemia (i.e. iron deficiency, malignancy, infection, etc.) before initiating treatment with an ESA or hypoxia-inducible factor-prolyl hydroxylase inhibitor (HIF-PHI). After all correctable causes of anemia are addressed, KDIGO suggests using ESAs as first-line therapy for treating anemia in patients with CKD rather than HIF-PHIs. Although clinical trials have revealed noninferiority of HIF-PHIs versus ESAs for efficacy as treatment for anemia, some studies suggested a higher risk of major adverse cardiovascular events and vascular access thrombosis with HIF-PHIs compared to ESAs in at least some CKD populations. For patients with CKD on dialysis, the guidelines recommend ESA therapy should be initiated when the Hb level is ≤ 9.0 to 10.0 g/dL. For patients with CKD who are not on dialysis, the decision to initiate ESA therapy should be individualized based on many factors (e.g., rate of Hb decline, prior response to iron therapy, transfusion risk, patient symptoms). In adults with anemia and CKD who are being treated with an ESA, KDIGO recommends targeting the Hb level to below 11.5 g/dl. For pediatric patients with anemia and CKD, the selection of an Hb target for ESA maintenance therapy should be individualized considering

potential benefits and harms. Baseline and periodic monitoring (e.g., iron, total iron-binding capacity, transferrin saturation, or ferritin levels) and instituting iron replacement when needed may be useful in limiting the need for ESAs, maximizing symptomatic improvement in patients, and determining the reason for inadequate response to ESAs. Iron deficiency can occur following continued ESA use. Therefore, ongoing iron supplementation is often required in most patients to maintain an optimal response.

Safety

ESAs carry a boxed warning for increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence.[1] These risks are greater when targeting higher hemoglobin levels.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Mircera in patients with conditions other than CKD who are on dialysis. The intent of this policy is to provide recommendations for uses other than anemia in patients with CKD who are on dialysis. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Mircera is recommended in those who meet one of the following:

FDA-Approved Indications

1. **Anemia in a Patient with Chronic Kidney Disease who is on Dialysis.** Approve for 3 years.

2. **Anemia in a Patient with Chronic Kidney Disease who is not on Dialysis.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has a hemoglobin < 10.0 g/dL; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient is currently receiving iron therapy; OR
       - **b)** Patient has adequate iron stores according to the prescriber; OR
   - **B)** Patient is Currently Receiving an Erythropoiesis-Stimulating Agent. Approve if the patient meets ALL of the following (i, ii, and iii):
     Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera).
     - **i.** If patient is < 18 years of age, the hemoglobin level has been stabilized by treatment with an erythropoiesis-stimulating agent, according to the prescriber; AND

Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera).

ii. Patient has a hemoglobin ≤ 12.0 g/dL; AND

iii. Patient meets ONE of the following (a or b):

a) Patient is currently receiving iron therapy; OR

b) Patient has adequate iron stores according to the prescriber.

Dosing. Approve ONE of the following dosing regimens (A or B):

A) Approve if the dose meets ALL of the following (i, ii and ii):

i. Patient is ≥ 18 years of age; AND

ii. Each dose is ≤ 180 mcg; AND

iii. Each dose is given no more frequently than once every 2 weeks; OR

B) Approve if the dose meets BOTH of the following (i and ii):

i. Each dose is ≤ 360 mcg; AND

ii. Each dose is given no more frequently than once monthly.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Mircera is not recommended in the following situations:

1. **Anemia Associated with Cancer in a Patient Receiving Myelosuppressive Cancer Chemotherapy.** Mircera is not indicated and not recommended for the treatment of anemia due to cancer chemotherapy.[1]

2. **To Enhance Athletic Performance.** Mircera is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

3. **Anemia due to Acute Blood Loss.** Use of Mircera is not appropriate in these types of situations.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Mircera® intravenous or subcutaneous injection [prescribing information]. Basking Ridge, NJ: Vifor Pharma; June 2024.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO 2026 Clinical Practice Guideline for the Management of Anemia in Chronic Kidney Disease (CKD). *Kidney Int*. 2026;109(1S):S1-S99.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Anemia in a Patient with Chronic Kidney Disease who is not on Dialysis**: For a Patient Currently Receiving an Erythropoiesis-Stimulating Agent, the age requirement was removed. Previously, the requirement was ≥ 18 years of age. A new requirement that according to the prescriber, the hemoglobin level has been stabilized by treatment with an erythropoiesis-stimulating agent for patients < 18 years of age was added. Dosing: A requirement was added that the patient must be ≥ 18 years of age for the every 2 week dosing regimen.	06/12/2024
Annual Revision	No criteria changes.	06/18/2025
Annual Revision	No criteria changes.	06/17/2026