# PRIOR AUTHORIZATION POLICY

**POLICY:** Erythropoiesis-Stimulating Agents – Mircera Prior Authorization Policy
- Mircera® (methoxy polyethylene glycol-epoetin beta intravenous or subcutaneous injection – Vifor Pharma)

**REVIEW DATE:** 07/20/2022

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## OVERVIEW

Mircera, an erythropoiesis-stimulating agent (ESA), is indicated for **anemia due to chronic kidney disease** (CKD), including adult patients on dialysis, adult patients not on dialysis, and pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.

Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life.[1] Mircera is not indicated 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.

Therapy should be initiated for patients with CKD on dialysis when the Hb level is < 10.0 g/dL and if the Hb level approaches or exceeds 11.0 g/dL, reduce or interrupt the dose of Mircera.[1] Patients with CKD not on dialysis, Mircera should be initiated when the Hb is < 10.0 g/dL and other considerations apply (e.g., patient is likely to need transfusions). 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.

## Guidelines

The Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for anemia in CKD (2012) state that for adults with CKD on dialysis ESA therapy should be used to avoid having the Hb concentration fall below 9.0 g/dL by initiating ESA therapy when the Hb is between 9.0 and 10.0 g/dL.[2] The guidelines recommend against ESA therapy for adult patients with CKD who are not on dialysis when Hb levels are ≥ 10.0 g/dL. For adult patients with CKD who are not on dialysis with Hb levels < 10.0 g/dL, the decision whether to initiate ESA therapy should be individualized based on many factors (e.g., prior response to iron therapy, the risk of needing a transfusion, presence of symptoms). In general, ESAs should not be used to maintain Hb concentrations above 11.5 g/dL in adult patients with CKD. For pediatric patients with CKD, the Hb concentration in which ESAs should be initiated in the individual patient should be considered while being aware of the potential benefits and potential harms. In all pediatric patients with CKD receiving ESA therapy, the selected Hb concentration should be in the range of 11.0 to 12.0 g/dL. Iron supplementation can improve response to ESA therapy. 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, iron supplementation is required in most patients to maintain an optimal response.

## POLICY STATEMENT

Prior Authorization is recommended for prescription 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. 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 criteria:

### 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 the following criteria (A or B):
   - **A)** Initial Therapy. Approve if the patient meets the following criteria (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 the following criteria (i, ii, and iii):
     Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera).
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has a hemoglobin < 11.5 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.

## 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; August 2019.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int*. 2012;2(Suppl):279-335.