Drug Coverage Policy

Effective Date..... 10/1/2024
Coverage Policy Number IP0297
Policy Title..... Mircera

Erythropoiesis-Stimulating Agents – Mircera

- Mircera® (methoxy polyethylene glycol-epoetin beta intravenous or subcutaneous injection – Vifor)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW
Mircera, an erythropoiesis-stimulating agent (ESA), is indicated for the treatment of ***anemia due to chronic kidney disease*** *(CKD) including:*[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.*

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 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.[1] For adults with CKD 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 CKD patients 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 (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.

Medical Necessity Criteria

Mircera is considered medically necessary when ONE of the following criteria are met:

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, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera).
i. If the patient is < 18 years of age, according to the prescriber, the hemoglobin level has been stabilized by treatment with an erythropoiesis-stimulating agent; AND
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).
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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J0887	Injection, epoetin beta, 1 mcg, (for ESRD on dialysis)
J0888	Injection, epoetin beta, 1 mcg, (for non-ESRD use)

References

1. Mircera intravenous or subcutaneous injection [prescribing information]. Basking Ridge, NJ: Vifor Pharma; March 2023.
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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Updated** coverage policy title from *Methoxy polyethylene glycol-epoetin beta* to *Erythropoiesis-Stimulating Agents – Mircera*. **Patient Currently Receiving an Erytrhopoiesis-Stimulating Agent:** **Removed** age requirement; previously age requirement was >/= age 18 years. **Added** new requirement that the hemoglobin level has been stabilized by treatment with erythropoiesis-stimulating agents for patients less than age 18 years. **Dosing:** **Added** a requirement that the patient be age 18 years or more for the every 2 weeks dosing regimen.	10/1/2024

The policy effective date is in force until updated or retired.