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5.85.021

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	January 16, 2015
Subject:	Mircera	**Page:**	1 of 6

Last Review Date: December 13, 2024

Mircera

Description

Mircera (methoxy polyethylene glycol-epoetin beta)

Background
Mircera (methoxy polyethylene glycol-epoetin beta) is an erythropoiesis stimulating agent (ESA) that binds to progenitor stem cells and stimulates the production and differentiation of red blood cells (RBCs). Erythropoietin is made in the kidney and released into the blood stream in response to hypoxia; it then interacts with erythroid progenitor cells to increase RBC production. The production of endogenous erythropoietin is impaired with chronic kidney disease (CKD); thus, anemia is common in this population primarily due to this erythropoietin deficiency. Mircera is used to treat anemia caused by chronic kidney disease (1).

Regulatory Status
FDA-approved indication: Mircera is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia associated with chronic kidney disease (CKD) in: (1)

1. Adult patients on dialysis and adult patients not on dialysis.
2. Pediatric patients 3 months to 17 years of age on dialysis or not on dialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.

Limitations of Use: (1)
Mircera is not indicated and is not recommended for use:

- In the treatment of anemia due to cancer chemotherapy
- As a substitute for RBC transfusions in patients who require immediate correction of anemia

Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life (1).

Mircera contains a boxed warning regarding increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence. In controlled trials, patients experienced greater risks for serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) are administered when hemoglobin levels are greater than 11 g/dL (1).

Transferrin saturation should be at least 20% or serum ferritin at least 100 ng/mL prior to treatment with erythropoietin stimulating agents, to ensure adequate iron stores. Supplemental iron therapy should be administered to reach these levels before initiating (1).

Safety and effectiveness of Mircera in patients less than 3 months of age have not been established (1).

Related policies
Aranesp, Epoetin alfa agents

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Mircera may be considered **medically necessary** if the conditions indicated below are met.

Mircera may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Anemia associated with chronic renal failure

AND ALL of the following:

1. Serum ferritin ≥ 100 ng/ml
2. **NOT** used in combination with another erythropoiesis stimulating agent
3. **NOT** used for anemia due to cancer chemotherapy

AND ONE of the following:

a. If patient is **NOT** on dialysis
   - i. Initial treatment: Hemoglobin < 10 g/dl*
   - ii. Continuing treatment: Hemoglobin ≤ 10 g/dl*

b. If patient is **ON** dialysis
   - i. Initial treatment: Hemoglobin < 10 g/dl*
   - ii. Continuing treatment: Hemoglobin ≤ 11 g/dl*

Age 3 months to 17 years of age

Diagnosis

Patient must have the following:

Anemia associated with chronic renal failure

AND ALL of the following:

1. Serum ferritin ≥ 100 ng/ml
2. Hemoglobin ≤ 11 g/dl*
3. **NOT** used in combination with another erythropoiesis stimulating agent
4. **NOT** used for anemia due to cancer chemotherapy
5. Converting from another ESA after their hemoglobin level was stabilized

* If the hemoglobin level exceeds this level then the prescribing physician must confirm that the dose will be held or reduced until the hemoglobin level returns to the required level.

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Anemia associated with chronic renal failure

AND ALL of the following:

1. Serum ferritin ≥ 100 ng/ml
2. **NOT** used in combination with another erythropoiesis stimulating agent
3. **NOT** used for anemia due to cancer chemotherapy

AND ONE of the following:

a. If patient is **NOT** on dialysis
   i. Initial treatment: Hemoglobin < 10 g/dl*
   ii. Continuing treatment: Hemoglobin ≤ 10 g/dl*

b. If patient is **ON** dialysis
   i. Initial treatment: Hemoglobin < 10 g/dl*
   ii. Continuing treatment: Hemoglobin ≤ 11 g/dl*

Age 3 months to 17 years of age

Diagnosis

Patient must have the following:

Anemia associated with chronic renal failure

AND ALL of the following:

1. Serum ferritin ≥ 100 ng/ml
2. Hemoglobin ≤ 11 g/dl*
3. **NOT** used in combination with another erythropoiesis stimulating agent
4. **NOT** used for anemia due to cancer chemotherapy

* If the hemoglobin level exceeds this level then the prescribing physician must confirm that the dose will be held or reduced until the hemoglobin level returns to the required level.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Mircera (methoxy polyethylene glycol-epoetin beta) is an erythropoiesis stimulating agent (ESA) that binds to progenitor stem cells and stimulates the production and differentiation of red blood cells (RBCs). Mircera is used to treat anemia caused by chronic kidney disease. Mircera is not indicated in the treatment of anemia due to cancer chemotherapy and as a substitute for RBC transfusions in patients who require immediate correction of anemia. Mircera contains a boxed warning regarding increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence. Safety and effectiveness of Mircera in patients less than 3 months of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Mircera while maintaining optimal therapeutic outcomes.

References

1. Mircera [package insert]. Switzerland: Vifor (International) Inc.; April 2024.

Policy History

Date	Action
January 2015	Addition to PA
March 2015	Annual review and reference update
December 2016	Annual editorial review Policy number change from 5.10.21 to 5.85.21
September 2017	Annual editorial review and reference update
July 2018	Addition of the use of this agent for chronic renal failure in patients age 5 – 17 years of age to criteria and requirement of not used for anemia due to cancer chemotherapy
September 2018	Annual review
September 2019	Annual review
September 2020	Annual review
June 2021	Annual editorial review
June 2022	Annual review

June 2023	Annual review and reference update. Changed policy number to 5.85.021
March 2024	Annual review and reference update
May 2024	Per PI update, reduced age to 3 months and older
June 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.