Mircera

Description

Mircera (methoxy polyethylene glycol-epoetin beta)

Background
Mircera 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. People with anemia have a lower-than-normal number of RBCs. Mircera works like the human protein called erythropoietin to help your body make more RBCs. Mircera is used to reduce or avoid the need for RBC transfusion (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. Adult patients on dialysis and adult patients not on dialysis
2. 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

Limitations of Use:
Mircera is not indicated and is not recommended:

- 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 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. Mircera has another boxed warning of an increased incidence of thromboembolic reactions, some serious and life-threatening, in patients with cancer when treated with ESAs (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 efficacy of Mircera in patients less than 5 years 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 in patients 5 years of age and older for the treatment of anemia associated with chronic renal failure and if the conditions indicated below are met.

Mircera may be considered investigational in patients less than 5 years of age and 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 5 – 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. Patient is on hemodialysis
4. NOT used in combination with another erythropoiesis stimulating agent
5. NOT used for anemia due to cancer chemotherapy
6. 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**

5 – 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. Patient is on hemodialysis
4. **NOT** used in combination with another erythropoiesis stimulating agent
5. **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**

**Duration**

6 months

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**Rationale**

**Summary**

Mircera 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 greater risks for serious adverse cardiovascular reactions, and stroke when erythropoiesis-stimulating agents (ESAs) are administered when hemoglobin levels are greater than 11 g/dL. Mircera has another boxed warning of an increased incidence of thromboembolic reactions, some serious and life-threatening, in patients with cancer when treated with ESAs (1).

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

**References**


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**Policy History**

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<thead>
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<tbody>
<tr>
<td>January 2015</td>
<td>Addition to PA</td>
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<tr>
<td>March 2015</td>
<td>Annual review and reference update</td>
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<tr>
<td>December 2016</td>
<td>Annual editorial review</td>
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<tr>
<td></td>
<td>Policy number change from 5.10.21 to 5.85.21</td>
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<tr>
<td>September 2017</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>July 2018</td>
<td>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</td>
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<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.