Methoxy Polyethylene Glycol-Epoetin Beta (Dialysis)

NDC CODE(S)
59353-0400-XX - MIRCERA 30MCG/0.3ML Solution Prefilled Syringe (VIFOR)
59353-0401-XX - MIRCERA 50MCG/0.3ML Solution Prefilled Syringe (VIFOR)
59353-0402-XX - MIRCERA 75MCG/0.3ML Solution Prefilled Syringe (VIFOR)
59353-0403-XX - MIRCERA 100MCG/0.3ML Solution Prefilled Syringe (VIFOR)
59353-0404-XX - MIRCERA 150MCG/0.3ML Solution Prefilled Syringe (VIFOR)
59353-0405-XX - MIRCERA 200MCG/0.3ML Solution Prefilled Syringe (VIFOR)

DESCRIPTION

Endogenous erythropoietin is a primary growth factor for the development of red blood cells produced in the kidney and released into the bloodstream in response to hypoxia, increasing production in response to greater need for oxygenation. Individuals with chronic kidney disease have impaired production of erythropoietin. This erythropoietin deficiency is the primary cause of their anemia.

In response to a more efficient long-term provision of erythropoietin to individuals with chronic kidney disease, methoxy polyethylene glycol-epoetin beta was developed. It is an erythropoietin stimulating agent which differs from endogenous erythropoietin through the formation of a chemical bond with methoxy polyethylene glycol (PEG). It has greater activity in the body as well as increased half-life as compared to erythropoietin.

POLICY

- Methoxy polyethylene glycol-epoetin beta for the treatment of anemia associated with chronic kidney disease (CKD) is considered **medically necessary** if the medical appropriateness criteria are met. (See Medical Appropriateness below.)
- Methoxy polyethylene glycol-epoetin beta for the treatment of other conditions/diseases is considered, including, but not limited to, the treatment of anemia due to cancer chemotherapy or as a substitute for red blood cell transfusions in individuals who require immediate correction of anemia, **investigational**.

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Methoxy polyethylene glycol-epoetin beta is considered **medically appropriate** if ALL of the following criteria are met:
  - Diagnosis of anemia secondary to chronic kidney disease (CKD) if ANY ONE of the following:
    - Adult individual receiving dialysis and is 18 years of age or older
    - Pediatric individual is receiving hemodialysis and ALL of the following:
      - 5 years of age or older
      - Individual is converting from another erythropoiesis stimulating agent (ESA) after their hemoglobin was stabilized
  - Initiation of therapy, Hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) <30%
  - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated)
  - Individual has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/ml (mcg/L) and transferrin saturation (TSAT) ≥20% (measured within the previous 3 months for renewal)*
  - Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out
  - Individual does not have uncontrolled hypertension

This document has been classified as public information
RENEWAL CRITERIA

- Methoxy polyethylene glycol-epoetin beta is considered medically appropriate for renewal if ALL of the following criteria are met:
  - Individual continues to meet initial approval criteria identified below:
    - Lab values are obtained within 30 days of the date of administration (unless otherwise indicated)
    - Individual has adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/ml (mcg/L) and transferrin saturation (TSAT) ≥ 20% (measured within the previous 3 months for renewal)*
    - Other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out
    - Individual does not have uncontrolled hypertension
  - Previous dose was administered within the past 60 days
  - Anemia response compared to pretreatment baseline
  - Absence of unacceptable toxicity from the agent. Examples of unacceptable toxicity include the following: pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, Stevens-Johnson syndrome/toxic epidermal necrolysis, etc), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, uncontrolled hypertension), seizures, etc.
  - Diagnosis of anemia secondary to chronic kidney disease and ANY ONE of the following:
    - Pediatric individuals: Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
    - Adult individuals: Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33%

* Intravenous iron supplementation may be taken into account when evaluating iron status

- Functional iron deficiency (i.e., adequate iron stores with an insufficient supply of available iron) may occur in patients with chronic diseases, cancer, and/or in those currently receiving ESAs.
- Iron is not generally recommended in anemic patients with a Ferritin > 500 ng/mL
- Anemic patients with a Ferritin < 500 ng/mL AND TSAT < 50% may derive benefit from IV iron therapy in conjunction with ESA

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<tr>
<th>INDICATION(S)</th>
<th>DOSAGE &amp; ADMINISTRATION</th>
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<tbody>
<tr>
<td>Adults with CKD on Dialysis</td>
<td>Starting dose: 0.6 mcg/kg IV or SC once every 2 weeks</td>
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<tr>
<td>Maintenance dose: Once monthly dosing (at twice the every-two-week dose) may occur once Hb has been stabilized. Most commonly the dose ranges from 120 to 360 mcg every 4 weeks</td>
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<tr>
<td>Pediatrics with CKD on Hemodialysis</td>
<td>Administer intravenously once every 4 weeks in pediatric patients whose Hb level has been stabilized by treatment with another ESA.</td>
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<tr>
<td>Conversion from Epoetin alfa</td>
<td>4 x previous weekly epoetin alfa dose (Units)/125=dose given every 4 weeks e.g. 4 x 1500 units of epoetin alfa per week/125 = 48 mcg of Mircera every 4 weeks</td>
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<tr>
<td>Conversion from Darbepoetin alfa</td>
<td>4 x previous weekly darbepoetin alfa dose (mcg)/0.55 = dose given every 4 weeks e.g. 4 x 20 mcg of darbepoetin alfa per week/0.55 = 145.5 mcg of Mircera every 4 weeks</td>
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- Dose increases of 25% can be considered if after 4 weeks of initial therapy the hemoglobin has increased less than 1 g/dL and the current hemoglobin level is less than the indication specific level noted above
- Dose decreases of 25% or more can be considered if the hemoglobin rises rapidly by more than 1 g/dL in any 2-week period
- Avoid frequent dose adjustments. Do not increase the dose more frequently than once every 4 weeks; decreases can occur more frequently.
• Dose and frequency requested are the minimum necessary for the patient to avoid RBC transfusions. If patients fail to respond over a 12-week dose escalation period, further dose increases are unlikely to improve response and discontinuation of therapy should be considered.

LENGTH OF AUTHORIZATION

Coverage will be provided for 12 months and may be renewed.

Refer to DOSAGE LIMITS below

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee’s Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES


Medical Policy Manual  

Approved Revision: Do Not Implement until 9/1/20

EFFECTIVE DATE  
9/1/2020

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