BlueCross BlueShield
Federal Employee Program

MIRCERA

(methoxy polyethylene glycol-epoetin beta)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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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).

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.