Reference number(s)
2113-A

JURISDICTION SPECIFIC MEDICARE PART B

Mircera (methyl polyethylene glycol-epoetin beta)

POLICY

I. COVERED USES

The indication below is considered a covered benefit provided that all the approval criteria is met and the member has no exclusions to the prescribed therapy.

Anemia in patients with chronic kidney disease

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Support for the medical rationale for treatment including most recent blood pressure, including evidence that elevated pressures are being adequately controlled, weight in kilograms, date and results of hematocrit and hemoglobin levels prior to the initiation of erythropoiesis stimulating agent therapy and assessment that rules out other causative factors of anemia
B. Most recent hematocrit and hemoglobin reading
C. Documentation that hemoglobin and hematocrit levels are documented at the frequencies outlined for each indication and that doses are being titrated or withheld/re-initiated according to the requirements in the federal regulations
D. Dosage of Mircera and route of administration

III. EXCEPTIONS

The following exceptions applies to all requests:

A. The member must not have uncontrolled hypertension.
B. Prior to initiating therapy all other causes of anemia have been managed or ruled out.
C. The member's iron status must be monitored before and during treatment.

IV. CRITERIA FOR APPROVAL

Anemia in chronic kidney disease

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion

CVS caremark™

1. Authorization of 16 weeks may be granted for treatment of anemia in members with chronic kidney disease who are not receiving erythropoiesis stimulating agents (ESA) when all of the following criteria are met:
   i. The member is not receiving dialysis.
   ii. The member's iron stores have been assessed and the transferrin saturation is greater than or equal to 20% and the member's ferritin level are 100 ng/mL or greater.
   iii. The member will have hemoglobin levels assessed at least weekly until stable then monthly.
   iv. The pre-treatment hemoglobin level is less than 10 g/dL.
2. Authorization of 12 months may be granted for continuation of therapy for anemia in members with chronic kidney disease who are receiving erythropoiesis stimulating agents (ESA) when all of the following criteria are met:
   i. The member is not receiving dialysis.
   ii. The member's iron stores have been assessed and the transferrin saturation is greater than or equal to 20% and the member's ferritin level are 100 ng/mL or greater.
   iii. The member has responded to treatment by increases in hemoglobin levels of at least 1 g/dL after 12 weeks of therapy.
   iv. The dose will be reduced or interrupted if the hemoglobin exceeds 12 g/dL.

V. REFERENCES

1. Erythropoiesis Stimulating Agents LCD (L36276) Version R11. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 10, 2021.
2. Billing and Coding: Erythropoiesis Stimulating Agents (A57628) Version 3. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 10, 2021.

