Reference number(s)
5565-A

JURISDICTION SPECIFIC MEDICARE PART B

MIRCERA (methoxy polyethylene glycol-epoetin beta)

POLICY

I. COVERED USES

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

Anemia related to end-stage renal disease (ESRD) and Stages IIIb, IV and V chronic kidney disease (CKD)

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. For a complete list of requirements, please consult Billing and Coding: Erythropoiesis Stimulating Agents (A58982) and LCD – Erythropoiesis Stimulating Agents (L39237).

A. For patients receiving any erythropoiesis stimulating agent (ESA):
   1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
   2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
   3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
   4. For any ESA, the medical record must reflect that ESA therapy for the individualized patient is reasonable and necessary. The medical record must document the most recent blood pressure and demonstrate reasonable control not in significant excess of a baseline range for a given patient, weight in kilograms, date and results of hematocrit (HCT) or hemoglobin (Hb) level prior to the administration of ESA therapy, evidence of assessment ruling out other causative factors of anemia or, if causative factors are present, that they have been managed and that it is still necessary to initiate ESA (evaluation and treatment must occur at anytime after initiation of ESA as needed for lack of responsiveness, where applicable). The dosage and route of administration (as well as frequency, where applicable) must be documented.
   5. The medical record should reflect the clinical reason for dose changes and HCT levels outside the range of 30-36% (Hb levels 10-12 g/dL).
   6. Relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. The indication for ESA administration must be evident within the medical record.

7. Medical justification for any ESA doses that differ from FDA label instructions. Documentation of dose reductions, dose continuation at lowest dose to avoid recurrent RBC transfusions, and dose increases where applicable.
8. Pretreatment Hb/HCT results and iron storage laboratory results. In the case of low iron stores, documentation regarding treatment that was given in terms of repletion. Iron stores, as evidenced by a transferrin saturation of at least 20% and a ferritin level at least 100 ng/mL must be resulted in order to continue with ESA treatment. Where applicable, hematological parameters should be monitored at least weekly during therapy until Hb is stable and sufficient to minimize the need for transfusion, and then Hb should be monitored at least monthly; iron storage must be checked prior to dosage increases and at least every 3 months during ongoing ESA therapy.
9. There are very rare patients whose cardiac, pulmonary or other medical conditions warrant the use of ESAs to maintain a Hb/HCT higher than the FDA target levels discussed. Documentation to support this practice must be available upon request.

B. For dialysis patients:
   1. Use of the ESA for specific diagnoses indicating symptomatic anemia of chronic kidney disease (CKD) on dialysis
   2. Documentation must include dialysis schedule
   3. Most recent creatinine level within the past month prior to initiation or next dosing of ESA
   4. For ESRD patients on home dialysis, the following must be maintained in the medical record and available upon request: a care plan, evidence of home monitoring (including a record of the ESA supplied to the patient and a record of dose administered), patient instructions and patient selection protocol.
   5. If the initial dose of an ESA was administered in another setting (i.e. hospital, in a state outside our jurisdiction, or in another facility); subsequent office-administered ESA claims may prompt a Medicare Administrative Contractor request for documentation regarding clinical criteria supporting initial administration as well as the need to continue the ESA. This may require review of outside medical records and confirmation that needed pre-treatment lab results and evaluation were completed appropriately.

C. For non-dialysis CKD patients:
   1. Use of the ESA for specific diagnoses indicating symptomatic anemia of CKD not on dialysis
   2. Most recent creatinine level within the past month prior to initiation or next dosing of ESA
   3. Documentation must include stable baseline eGFR with the accompanying accurate, most specific stage of disease per ICD-10-CM
   4. If the initial dose of an ESA was administered in another setting (i.e. hospital, in a state outside our jurisdiction, or in another facility); subsequent office-administered ESAs must still meet all requirements. This may require review of outside medical records and confirmation that needed pre-treatment lab results and evaluation were completed appropriately.

III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:

A. Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis
B. The anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers
C. The anemia of cancer not related to cancer treatment
D. Any anemia associated only with radiotherapy

E. Prophylactic use to prevent chemotherapy-induced anemia
F. Prophylactic use to reduce tumor hypoxia
G. Patients with erythropoietin-type resistance due to neutralizing antibodies
H. Non-ESRD ESA services within the context of other medical conditions for which resolution would be reasonably expected prior to starting or continuing ESA administration (including, but not limited to: iron/vitamin B12/folate deficiencies, G6PD deficiency, pyridoxine deficiency, various forms of hemolysis, hereditary spherocytosis, and pure red cell aplasias).
I. ESA use within the context of uncontrolled hypertension.
J. ESA use to replace RBC transfusions in members who need immediate urgent correction of anemia.

IV. CRITERIA FOR APPROVAL

Note: The following causes of anemia should be considered, documented, and corrected before starting or continuing ESA therapy for any of the covered indications: iron deficiency; underlying infection, inflammatory or malignant processes; underlying hematological disease; hemolysis; vitamin deficiencies (e.g. folic acid or B12); blood loss- overt or occult; aluminum intoxication; osteitis fibrosis cystica; or pure red blood cell aplasia.

A. Anemia of end stage renal disease (ESRD) in a member on dialysis
Authorization of 12 weeks may be granted for treatment of anemia of ESRD in a member on dialysis when all of the following criteria is met:
1. Member has a diagnosis of end stage renal disease.
2. Hb < 10 g/dL or HCT < 30% at initiation of therapy.
3. The provider will document the most recent creatinine within the past month prior to initiation or next dosing of ESA.

B. Anemia of chronic kidney disease (CKD) in a member not on dialysis
Authorization of 12 weeks may be granted for treatment of anemia of CKD in a member not on dialysis when all of the following criteria is met:
1. Hb < 10 g/dL or HCT < 30% at initiation of therapy.
2. Glomerular filtration rate (GFR) < 45 mL/min/1.73m^2.
3. The provider will document the most recent creatinine within the past month prior to initiation or next dosing of ESA.

V. CONTINUATION OF THERAPY

Note: The following causes of anemia should be considered, documented, and corrected before starting or continuing ESA therapy for any of the covered indications: iron deficiency; underlying infection, inflammatory or malignant processes; underlying hematological disease; hemolysis; vitamin deficiencies (e.g. folic acid or B12); blood loss- overt or occult; aluminum intoxication; osteitis fibrosis cystica; or pure red blood cell aplasia.

Anemia of ESRD in a member on dialysis, Anemia of CKD in a member not on dialysis
Authorization of 12 weeks may be granted when all of the following criteria is met:
1. The goal of therapy is to maintain a stable Hb and HCT, with target ranges of 10-12 g/dL and 30-36% respectively.
2. The provider will document the most recent creatinine within the past month prior to next dosing of ESA.

VI. DOSAGE AND ADMINISTRATION

The starting dose and subsequent dose adjustments must be in accordance with FDA-approved labeling or dosing provided in Billing and Coding: Erythropoiesis Stimulating Agents (A58982) or LCD – Erythropoiesis Stimulating Agents (L39237). Doses must be titrated according to the patient's response.

VII. REFERENCES

1. Erythropoiesis Stimulating Agents LCD (L39237) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 15, 2022.
2. Billing and Coding: Erythropoiesis Stimulating Agents (ESA) (A58982) Version R2. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed September 29, 2022.
3. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; June 2018.