Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21)

Policy Number 110.21  Approved By UnitedHealthcare Medicare Reimbursement Policy Committee  Current Approval Date 09/11/2013

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY
This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy. This information is intended to serve only as a general resource regarding UnitedHealthcare’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Summary

Overview

The ESAs stimulate the bone marrow to make more red blood cells and are United States Food and Drug Administration (FDA) approved for use in reducing the need for blood transfusion in patients with specific clinical indications. The FDA has issued alerts and warnings for ESAs administered for a number of clinical conditions, including cancer. Published studies report a higher risk of serious and life-threatening events associated with oncologic uses of ESAs.

Reimbursement Guidelines

Nationally Covered Indications

The ESA treatment for the anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is only reasonable and necessary under the following specified conditions:

- The hemoglobin level immediately prior to initiation or maintenance of ESA treatment is <10 g/dL (or the hematocrit is <30%).
- The starting dose for ESA treatment is the recommended FDA label starting dose, no more than 150 U/kg/3 times weekly for epoetin and 2.25 mcg/kg/1 time weekly for darbepoetin alpha. Equivalent doses may be given over other approved time periods.
- Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10 g/dL (or hematocrit is <30%) 4 weeks after initiation of therapy and the rise in hemoglobin is > 1g/dL (hematocrit > 3%).
- For patients whose hemoglobin rises <1 g/dl (hematocrit rise <3%) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains <10 g/dL after the 4 weeks of treatment (or the hematocrit is <30%), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the hemoglobin rises <1 g/dl (hematocrit rise <3 %) compared to pretreatment baseline by 8 weeks of treatment.
- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in hemoglobin >1 g/dl (hematocrit >3%) over 2 weeks of treatment unless the hemoglobin remains below or subsequently falls to <10 g/dL (or the hematocrit is <30%). Continuation and reinstitution of ESA therapy must include a dose reduction of 25% from the previously administered dose.
- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

Nationally Non-Covered Indications

The ESA treatment is not reasonable and necessary for beneficiaries with certain clinical conditions, either...
Reimbursement Policy

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because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use. These conditions include:

- Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis;
- The anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers;
- The anemia of cancer not related to cancer treatment;
- Any anemia associated only with radiotherapy;
- Prophylactic use to prevent chemotherapy-induced anemia;
- Prophylactic use to reduce tumor hypoxia;
- Patients with erythropoietin-type resistance due to neutralizing antibodies; and
- Anemia due to cancer treatment if patients have uncontrolled hypertension.

Other
Local Medicare contractors may continue to make reasonable and necessary determinations on all other uses of ESAs not specified in this NCD.

See the Medicare Benefit Policy Manual, chapter 11, section 90 and chapter 15, section 50.5.2 for coverage of ESAs for end-stage renal disease related anemia.

CPT/HCPCS Codes

**HCPCS J0882, J0886, J0890, Q2047 and Q4081 are addressed in the Erythropoietin Stimulating Agent (ESA) Reimbursement Policy**

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<th>Description</th>
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<td>Injection, darbepoetin alfa, 1 mcg (non-ESRD use)</td>
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<td>J0885</td>
<td>Injection, epoetin alfa, (for non-ESRD use), 1000 units</td>
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<th>Modifiers</th>
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<tr>
<td>EA</td>
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References Included (but not limited to):

**CMS NCD**
NCD 110.21 Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions

**CMS LCD(s)**
Numerous LCDs

**CMS Article(s)**
Numerous Articles

**CMS Benefit Policy Manual**
Chapter 6; § 10 Medical and Other Health Services Furnished to Inpatients of Participating Hospitals, § 30 Drugs and Biologicals
Chapter 11; § 90 Medicare as a Secondary Payer
Chapter 15; § 50.5.2 Erythropoietin (EPO), § 50.5.2.1 Requirement for Medicare Coverage for EPO, § 50.5.2.2 Medicare Coverage of Epoetin Alfa (Procrit) for Preoperative Use

**CMS Claims Processing Manual**
Chapter 8; § 60 Separately Billable ESRD Items and Services, § 60.4 Erythropoietin Stimulating Agents (ESAs)
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Chapter 17; § 40.1 Discarded Erythropoietin Stimulating Agents for Home Dialysis, § 60 DMEPOS Suppliers Require a License to Dispense Drugs, § 80.8 Reporting of Hematocrit and/or Hemoglobin Levels, § 80.9 Required Modifiers for ESAs Administered to Non-ESRD Patients, § 80.10 Hospitals Billing for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Non-ESRD Patients, § 80.11 Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs), § 80.12 Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy

UnitedHealthcare Medicare Advantage Coverage Summaries
Dialysis Services
Medications/Drugs (Outpatient/Part B)

UnitedHealthcare Reimbursement Policies
Erythropoietin Stimulating Agent (ESA)

MLN Matters
Article MM5699, Reporting of Hematocrit or Hemoglobin Levels on All Claims for the Administration of Erythropoiesis Stimulating Agents (ESAs), Implementation of New Modifiers for Non-ESRD ESA Indications, and Reporting of Hematocrit or Hemoglobin Levels on all Non-ESRD, Non-ESA Claims Requesting Payment for Anti-Anemia Drugs

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<tr>
<th>Date</th>
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<tr>
<td>09/11/2013</td>
<td>See the Erythropoietin Stimulating Agent (ESA) Reimbursement Policy</td>
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