

National Coverage Determination

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

Contractor's Determination Number

INJ-040

Contractor Name

Wisconsin Physicians Service (WPS)

Contractor Number

00951, 00952, 00953, 00954
05101, 05201, 05301, 05401,
05102, 05202, 05302, 05402, 52280

Contractor Type

Carrier B
Fiscal Intermediary A
MAC A
MAC B

Primary Geographic Jurisdiction

Carrier B: Wisconsin, Illinois, Michigan, Minnesota

Fiscal Intermediary A: Alaska, Alabama, Arizona, Arkansas, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, Wyoming, U.S. Virgin Islands

MAC A/B: Iowa, Missouri, Nebraska, Kansas

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Effective Date

Multiple

Implementation Date

N/A

CMS National Coverage Policy

Medicare National Coverage Determinations Pub 100-03; Transmittal 80

Date: JANUARY 14, 2008; Change Request 5818

110.21 - Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (Rev. 80; Issued: 01-14-08; Effective: 07-30-07; Implementation: 04-07-08)

Medicare National Coverage Determinations Pub 100-03; Transmittal 80

Date: JANUARY 14, 2008; Change Request 5818

110.21 - Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions
NEW / REVISED MATERIAL; Effective Date: JULY 30, 2007

Modifiers: January 1, 2008; Implementation Date: APRIL 7, 2008

A. General

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.

B. 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 ≥ 1 g/dL (hematocrit $\geq 3\%$).*
- *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 reinstatement 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.*

C. Nationally Non-Covered Indications

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

D. 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.

(This NCD last reviewed July 2007.)

Effective Date: 07/30/2007, Implementation: 04-07-08
Date Published: 10/01/2009 (Article); 06/01/2008, Article; 03/01/2008
Revision & Date: *10/01/2011 Expanded to all Web sites; 10/ 10/01/2009, Addition of ICD-9 code 285.3 -Antineoplastic chemotherapy induce induced anemia replaces other coding instructions; 06/01/2008, correction of typographical error ≥; 04/01/2008, addition of ICD-9 codes

[View the Billing and Coding Guidelines associated with this NCD](#)