

COVERAGE OF ERYTHROPOIESIS STIMULATING AGENTS (ESAS)

Coverage of Erythropoiesis Stimulating Agents (ESAs) for anemia of cancer will be terminated March 19, 2007 based on new evidence that indicates this may not be safe and effective treatment.

Due to the results of a recent study, the *USPDI* has removed coverage for this condition. There are now new boxed warnings for these drugs.

WPS, like all other Medicare contractors, is bound by the Medicare Benefit Policy Manual (CMS Pub 100 -02). Section 50.4.5 of this national document states:

“If a use is identified as not indicated by CMS or the FDA, or it’s use is specifically identified as not indicated in one or more of the three compendia mentioned or if the carrier determines, based on peer reviewed literature, that a particular use of the drug is not safe and effective, the off-label use is not supported and, therefore, the drug is not covered.”

Similarly, in the Program Integrity Manual (CMS Pub 100-08) the following section indicates that Medicare carriers can restrict coverage without going to a Carrier Advisory Committee (CAC) if they receive CMS Regional Office approval. Our regional office, has approved this restriction of coverage.

**PIM 13.7.3 - LCDs That Do Not Require a Comment and Notice Period
(Rev. 71, 04-09-04)**

Revised LCD Being Issued for Compelling Reasons - SHALL OBTAIN RO (for PSCs, the GTL, Co-GTL, and SME) APPROVAL - For example, a highly unsafe procedure/device.

The policy will be changed as follows.

LCD Title

Erythropoiesis Stimulating Proteins
Epoetin alfa (EPO), Darbepoetin alfa (DPA)

Contractor's Determination Number

INJ-023

Indications and Limitations of Coverage and/or Medical Necessity

The following section will be removed

3. **Anemia associated with non-myeloid malignancy**
The anemia must be due to the non-myeloid malignancy itself, chemotherapy (current or previous) and/or radiotherapy (current or

previous). The patient must have documented anemia described as follows:

The patient must have, within the past 30 days, HCT 33 or below or HGB 11 or below, before coverage by WPS Medicare will begin. Where the patient has required a blood or red cell transfusion within the past month, you may use the most recent HCT or HGB before the transfusion.

ICD-9 Codes that Support Medical Necessity

1. **EPO or DPA for ESRD on Dialysis**
 - J0886** Injection of EPO, per 1000 units
 - J0882** Injection darbepoetin alfa, per 1mcg

285.21- anemia in end-stage renal disease.

2. **EPO or DPA for indications other than ESRD on dialysis**
 - J0885** Injection of EPO, per 1000 units
 - J0881** Injection of DPA, per 1 mcg

The crossed out section will be removed.

- a. ~~For non-myeloid malignancies or multiple myeloma, code 285.22 - anemia in neoplastic disease plus one of the following: 140.0-204.91, 230.0-238.6, 238.8-239.9, 273.3.~~
- a. For Anemia of Chronic disease use ICD-9 code 285.29. No other ICD-9 code is needed.
- b. Use both the anemia code (285.8 or 285.9) and one of the following codes or combination of codes, according to the disease that is being treated:
 - i. Chronic renal disease (CRD) (585.1 - 585.9) - Use one of these codes to indicate CRD not yet on dialysis.
 - ii. AZT treatment with AIDS (042, 079.53)
 - *iii For chemotherapy induced anemia use 995.20 to indicate the anemia is secondary to chemotherapy properly administered to treat neoplastic or other diseases. Also indicate the diagnostic code for the disease being treated.
(Three diagnosis codes will be required when billing for chemotherapy induced anemia: 285.8 or 285.9 to indicate the anemia; 995.20 to indicate the chemotherapy and a third code to indicate the underlying condition.)
 - *iv. For multiple myeloma (203.00)
 - v. Myelodysplastic syndrome (238.72, 238.73, 238.74, 238.75, 284.9, 285.0),
 - Chronic myelomonocytic leukemia (CMML)

- vi. Prophylactic pre-operative use (V07.8) for reduction of allogenic blood transfusions prior to elective hip and knee replacement surgery.

Note: ICD-9 codes must be coded to the highest level of specificity.