

Pinnacle Business Solutions Inc (PBSI) has recently updated our medical policies for Erythropoiesis-Stimulating Agents (ESAs) based upon the important information released by the FDA.

Pinnacle Medicare Services Medicare Part A & B

Important Notice from the Medical Directors **LCD Revisions for EPOgen and Darbopoetin Alfa (DPO)**

The FDA has issued revised product labeling including a Black Box Warning for the erythropoietin stimulating agents (ESAs) EPO (EPOGEN, Epoetin, Procrit) and Aranesp (Darbopoetin Alfa). The revised package labels and warnings address the use of ESAs:

- for patients with anemia associated with malignancy that are not anemic as a result of treatment with chemotherapeutic drugs;
- for cancer patients;
- in the lowest dose possible to increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion;
- when administered to target a hemoglobin greater than 12 g/dL; and
- pre-operatively for reduction of allogeneic red blood cell transfusions in patients who were not receiving prophylactic anticoagulation.

Medicare off-labeled drug coverage instructions per *Medicare Benefit Policy Manual* Pub. 100-02, Chapter 15, Section 50.4.2, *Unlabeled Use of a Drug* states:

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the Food and Drug Administration (FDA). FDA-approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice ...

In view of these developments, PBSI will not cover ESAs for the indication of anemia of malignancy in patients who are not anemic as a result of cancer chemotherapy. We will continue to cover the use of ESAs in patients with symptomatic anemia who have been rendered anemic as a result of cancer chemotherapy.

Due to the safety concerns outlined by the FDA and with approval of our CMS Regional Office, this change is being made without the usual notice and comment period. The coverage changes will be **effective for dates of service on or after March 29, 2007**, for claims received on or after **March 29, 2007**.

The following revised Part B Local Coverage Determinations (LCD) will be posted to the PBSI Web site with the coverage change:

- EPO/Darbopoetin Alfa Administration for Secondary Anemia, AC-05-004,
- EPO/Darbopoetin Alfa-Preoperative, AC-05-006,

- EPO/Darbepoetin Alfa for Treatment of Anemia Associated AZT Therapy, AC-05-005,
- EPO/Darbepoetin Alfa for Treatment of Anemia Associated with Chronic Renal Failure, AC-05-007

The following revised Part A Local Coverage Determinations (LCD) will be posted to the PBSI Web site with the coverage change:

- EPO/Darbepoetin Alfa Administration for Secondary Anemia, ARA-05-004,
- EPO/Darbepoetin Alfa-Preoperative, ARA-05-006,
- EPO/Darbepoetin Alfa for Treatment of Anemia Associated AZT Therapy, ARA-05-005,
- EPO/Darbepoetin Alfa for Treatment of Anemia Associated with Chronic Renal Failure, ARA-05-007 Revised Coding Instructions

As noted in the Secondary Anemia policy (AC-05-004 or ARA-05-004), there is now a primary and secondary diagnosis relationship for anemia secondary to cancer chemotherapy. The primary ICD-9-CM diagnosis code MUST be 285.9, used to indicate symptomatic anemia. The secondary ICD-9-CM diagnosis codes are V58.11, V67.2, or E933.1. Use V58.11 or E933.1 to represent a patient with non-myeloid malignancy actively receiving chemotherapy that is causing the anemia. Use V67.2 to represent a patient with anemia caused by chemotherapy received for a non-myeloid malignancy.

Use ICD-9-CM code 285.29 (primary) with 070.54, 238.72-238.75, or 714.0-714.4 (secondary) to represent patients with anemia due to either hepatitis C (patients being treated with ribavirin and interferon alfa or ribavirin and peginterferon alfa), myelodysplastic syndrome, or rheumatoid arthritis.