

## Medicare Part B

### Revised LCD for Erythropoietic Agents Effective March 5, 2007

Medicare will not reimburse the use of Darbepoetin (DPA, Aranesp®) for the treatment of the anemia of cancer effective March 5, 2007. Noridian Administrative Services (NAS) undertakes this action in accordance with CMS instructions on LCD revisions "Being Issued for Compelling Reasons." (*Program Integrity Manual*, IOM 100-8, Chapter 13, Section 13.7.3). In February, the FDA issued an alert, the USP DI described the treatment of the anemia of cancer with darbepoetin as "unaccepted" and Amgen released a warning letter to healthcare professionals stating that DPA "should be used only in accordance with its approved product labeling." These actions were taken following Amgen's announcement of excess mortality in patients receiving DPA for the treatment of anemia associated with cancer. (Note: This non-coverage determination does not apply to the use of DPA in the treatment of the anemia secondary to chemotherapy.)

Additionally, the FDA Alert, published February 16, 2007, was careful to point out the following:

*"ESAs [erythropoietic stimulating agents] are not FDA approved to treat anemia in cancer patients not receiving chemotherapy. The findings in this study of Aranesp may apply to other ESAs."*

NAS intends a careful review of the coverage of erythropoietin (EPO) for this indication in upcoming weeks and welcomes the input of helpful, peer-reviewed literature on this topic.

**Applies to the states of: AK, AZ, CO, HI, IA, MT, ND, NV, OR, SD, UT, WA & WY.**

**Effective Date: March 5, 2007**

#### **Sources:**

*Medicare Benefit Policy Manual* (IOM 100-02), Chapter 15, Section 50.4.2: Unlabeled Use of a Drug:

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 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...

Micromedex-Thomson Healthcare, Darbepoetin Alfa (Systemic), in *Drug Information for the Health Care Professional: USP-DI*, February 2007:

**"Unaccepted** - Anemia associated with malignancy (treatment)—Darbepoetin alfa not indicated for the treatment of anemia associated with neoplastic diseases."

*FDA Information for Health Professionals, Erythropoiesis Stimulating Agents (ESA)* at <http://www.fda.gov/cder/drug/infopage/RHE/default.htm>.

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