

NEW FROM FCSO WEBSITE: - March 21, 2007

NESP: Darbepoetin alfa (Aranesp[®]) (novel erythropoiesis stimulating protein [NESP])—LCD Revision

The local coverage determination (LCD) for darbepoetin alfa (Aranesp) (novel erythropoiesis stimulating protein [NESP]) was last updated February 26, 2007. Since that time, the FDA (U.S. Food and Drug Administration) notified health care professionals of new safety information for erythropoiesis-stimulating agents (ESAs) Aranesp (darbepoetin alfa), Epogen[®] (epoetin alfa), and Procrit[®] (epoetin alfa), drugs used to treat certain causes of anemia. Four new studies in patients with cancer found a higher chance of serious and life-threatening side effects or death with the use of ESAs. These research studies were evaluating an unapproved dosing regimen, a patient population for which ESAs are not approved, or a new unapproved ESA. In another study, patients scheduled for orthopedic surgery had a higher rate of deep venous thrombosis when treated with ESA at the approved dose. This new information is consistent with risks found in two clinical studies in patients with chronic renal failure treated with an unapproved regimen of an ESA that were reported in November 2006.

The Agency will present this new information to the Oncologic Drugs Advisory Committee on May 10, 2007. The FDA will seek advice on the need for additional labeling changes and/or additional studies to further assess safety.

Medicare covers all labeled (FDA-approved) indications for the drugs, though issues of dose and endpoints have been raised by the recent studies. Also, First Coast Service Options, Inc. (FCSO), as well as other Medicare contractors, allows off-label (non FDA-approved) drug coverage based on the local coverage determination process that includes review of the evidence based medical literature and input from practicing physicians. ESAs currently have coverage for off-label indications such as the anemia of cancer not due to concurrent chemotherapy for Medicare patients in Connecticut and Florida. Given the preliminary data and warning released by the manufacturer to health care professionals and now the FDA notification, FCSO has evaluated all off-label coverage of darbepoetin alfa (Aranesp) and will be removing coverage for anemia of malignancy **not** due to concurrent chemotherapy for Medicare patients in Connecticut and Florida.

With this decision, the LCD for Aranesp (darbepoetin alfa), will be revised in several ways:

- Under the “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD:
- Removed the indication for anemia of malignancy not due to concurrent chemotherapy.
- Revised the FDA-approved covered indications to read exactly per the FDA-approved label.
- Under general indications and limitations, removed recommended dosing for anemia associated with malignancy not due to concurrent chemotherapy.
- Under the “Utilization Guidelines” section of the LCD:
- Added a statement about endpoints for administering Aranesp for anemia associated with concurrent chemotherapy and added language from the FDA-approved label regarding the safety and effectiveness of Aranesp.

- Under the “ICD-9 Codes that Support Medical Necessity” section of the LCD for HCPCS code J0881:

- Removed ICD-9-CM codes 205.00-205.91, 206.00-206.91 and 207.00-208.91 as these ICD-9-CM codes are no longer supported as medically necessary.

- Added a dual diagnosis requirement for the following ICD-9-CM codes:

140.0-149.9	150.0-159.9	160.0-165.9	170.0-176.9	179-189.9	190.0-199.1
200.00-200.88	201.00-201.98	202.00-202.98	203.00-203.81	204.00-204.91	230.0-234.9
235.0-235.9	236.0-236.99	237.0-237.9	238.0	238.1	238.2
238.3	238.4	238.5	238.6	238.8	238.9
239.0-239.9	995.20	995.29	V58.11		

One of the malignancy ICD-9-CM codes in the table above and one of the following ICD-9-CM: 995.20, 995.29 and V58.11 must be billed when Aranesp is given for anemia of malignancy related to concomitantly administered chemotherapy. ICD-9-CM V58.11 would be billed with a malignancy code if the patient is currently receiving chemotherapy treatment. ICD-9-CM 995.20 or 995.29 would be billed with one of the malignancy codes if the patient has received chemotherapy treatment and it has been no more than 120 days since the last chemotherapy treatment.

FCSO is making these revisions in accordance with the Program Integrity Manual, Pub 100-08, Chapter 13, Section 13.7.3, “being issued for compelling reasons.”

CMS announced on March 14, 2007, the opening of a national coverage analysis (NCA) on the use of ESAs for the conditions other than end-stage renal disease (ESRD). This is the first step toward issuing a national coverage determination (NCD). Information on this national coverage analysis may be found at <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=203>.

FCSO is continuing to evaluate all off-label coverage of darbepoetin alfa (Aranesp) and epoetin alfa (Epogen, Procrit). FCSO will communicate to physicians and allied providers if and when such off-label indications are removed from the local coverage determinations.

Effective Date

These revisions to the LCD are effective for services **rendered on or after April 19, 2007**. The full text for this LCD is available through the Connecticut provider education website at <http://www.connecticutmedicare.com>, and the Florida provider education website at <http://www.floridamedicare.com> on or after this effective date. v