CMS Manual System

Pub. 100-02 Medicare Benefit Policy

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 8 | **Date: MARCH 5, 2004**

CHANGE REQUEST 2984

THE ATTACHED CR REPLACES THE CONFIDENTIAL REQUIREMENT, FILE NAME R19_OTN COMMUNICATED ON NOVEMBER 7, 2003. PLEASE DISCARD CR 2984 DATED NOVEMBER 7, 2003.

WE HAVE CORRECTED THE FDA INDICATORS FOR EPOGEN AND ARANESP IN SECTION 90 OF THE MEDICARE BENEFIT POLICY MANUAL.

I. SUMMARY OF CHANGES: We are making changes to reflect coverage policy for Darbepoetin Alfa (Aranesp).

NEW/REVISED MATERIAL - EFFECTIVE DATE: April 1, 2004
***IMPLEMENTATION DATE: April 5, 2004**

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	11/90/Epoetin (EPO)

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

90 - *Erythropoietin*

(Rev 8, 03-19-04)

A3-3168.D, PR 1-2710.3, RDF-207.5, B3-4273

Erythropoietin produced primarily in the kidney, is the principal factor regulating red blood cell production. Epoetin alfa *(EPO) and darbepoetin alfa (Aranesp) are biologicals that work in the same way as endogenous erythropoietin. EPO and Aranesp are covered under the Part B benefit for the treatment of anemia associated with ESRD patients who are on dialysis.*

Epoetin is a biologically engineered protein that stimulates the bone marrow to make new red blood cells. Epogen and Aranesp are both FDA approved for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis. EPO*/Aranesp* is covered for this indication when it is furnished incident to a physician's service. *Generally, ESRD patients with symptomatic anemia considered for initiation of EPO/Aranesp therapy should have a hematocrit less than 30 or hemoglobin less than 10; ESRD patients who have been receiving EPO/Aranesp therapy should have a hematocrit between 30 and 36.*

In addition to coverage incident to a physician service, EPO*/Aranesp* is covered for the treatment of anemia for *ESRD* patients who are on *maintenance* dialysis when:

- It is administered in the renal dialysis facility; or
- It is self-administered in the home by any dialysis patient (or patient caregiver) who is determined competent to administer the drug and meets the other conditions detailed below;
- Both Method I (Composite Rate) and Method II (direct dealing) beneficiaries may obtain coverage for self-administered EPO*/Aranesp*. For Method II home patients, their single supplier of home dialysis equipment and supplies would furnish the EPO*/Aranesp* and bill Medicare through the DMERC. If an ESRD facility provides EPO*/Aranesp*, the facility would bill the intermediary.

NOTE: Payment may not be made for EPO*/Aranesp* under the incident to provision when EPO*/Aranesp* is administered in the renal facility. Program payment may not be made for EPO*/Aranesp* furnished by a physician to a home patient for self-administration.

For payment of EPO*/Aranesp*, see the Medicare Claims Processing Manual, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §60.4.

Medicare covers EPO*/Aranesp* including items related to its administration for dialysis patients who use EPO*/Aranesp* in the home when the following conditions are met:

A - Patient Care Plan

A dialysis patient who uses EPO/*Aranesp* in the home must have a care plan for monitoring home use of EPO/*Aranesp* that includes the following:

1. Review of diet and fluid intake for aberrations as indicated by hyperkalemia and elevated blood pressure secondary to volume overload;

2. Review of medications to ensure adequate provision of supplemental iron;

3. Ongoing evaluations of hematocrit and iron stores;

4. Reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume;

5. Method for physician follow-up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results;

6. Training of the patient to identify the signs and symptoms of hypotension and hypertension; and

7. The decrease or discontinuance of EPO/*Aranesp* if hypertension is uncontrollable.

B - Patient Selection

The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

1. Pre-selection monitoring - The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

2. Conditions the patient must meet - The assessment must find that the patient meets the following conditions:

    a. Is a dialysis patient;

    b. Has a hematocrit (or comparable hemoglobin level) that is as follows:

        (1) For a patient whom is initiating EPO/*Aranesp* treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO/*Aranesp* despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. Patients with severe angina, severe pulmonary distress, or severe hypotension may require EPO/*Aranesp* to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.

        (2) For a patient who has been receiving EPO/*Aranesp* from the facility or the physician, between 30 and 36 percent; and

c. Is under the care of:

(1) A physician who is responsible for all dialysis-related services and who prescribes the EPO/*Aranesp* and follows the drug labeling instructions when monitoring the EPO home therapy; and

(2) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO/*Aranesp* therapy.

3. The assessment must find that the patient or a caregiver meets the following conditions:

- Is trained by the facility to inject EPO/*Aranesp* and is capable of carrying out the procedure;
- Is capable of reading and understanding the drug labeling;
- Is trained in, and capable of observing, aseptic techniques; and
- Is capable of understanding and implementing a plan for the care and storage of a drug. The assessment must find that EPO/*Aranesp* can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

C - Responsibilities of Physician or Dialysis Facility

The patient's physician or dialysis facility must:

- Develop a protocol that follows the drug label instructions;
- Make the protocol available to the patient to ensure safe and effective home use of EPO/*Aranesp*;
- Through the amounts prescribed, ensure that the drug on hand at any time does not exceed a 2-month supply;
- Maintain adequate records to allow quality assurance for review by the network and State survey agencies. For Method II patients, current records must be provided to and maintained by the designated back-up facility; and,
- Submit claims for EPO in accordance with the Medicare Claims Processing Manual, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §60.4.1.
- Submit claims for Aranesp in accordance with the Medicare Claims Processing Manual, Chapter 17, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §60.7.1.