

Medicare to tighten ESA claims monitoring policy

Posted on: 07/20/2007

 PRINT

WASHINGTON —In response to safety concerns, the Centers for Medicare & Medicaid Services said today that it is tightening its erythropoiesis-stimulating agent monitoring by placing stricter payment penalties when doses exceed a certain level in dialysis patients.

"Since the last modification to this policy in October 2006, there have been several publications and a Food and Drug Administration 'black box' warning that emphasize the risks facing ESRD patients who receive large doses of ESAs and have hemoglobin levels above 12 g/dL," CMS said in a press release.

ESAs, such as Amgen's Epogen and Aranesp, are used to treat anemia and reduce the need for blood transfusions in chronic kidney disease patients. Current Medicare policy states that a dialysis patient's hemoglobin range, which measures the extent of a patient's anemia, should be maintained between 10 and 12 g/dL.

In its revised policy, CMS will require an ESA dose reduction of 50 percent if a dialysis patient's hemoglobin exceeds 13 g/dL for three consecutive months. The clinic will be reimbursed at the reduced rate regardless if the reduction was made. Current CMS policy requires the clinic to reduce ESA dosage by 25 percent for the same conditions.

In addition, under the revised policy, Medicare will not pay for Epogen dosages that exceed 400,000 IUs per month or Aranesp doses greater than 1,200 mcg per month. The limits have been lowered from 500,000 IU and 1,500 mcg, respectively. "Dosages at these levels are unlikely and are generally the result of typographical errors rather than accurate dosage reports," CMS said.

The new policy will go into effect for claims on and after Jan. 1, 2008.

"We feel strongly that these revisions will support the clinically sound and prudent management of anemia in dialysis patients," said Barry Straube, MD, CMS' chief medical officer, who is also a nephrologist.

Although the policy is final, CMS said it will still welcome public comment on the modification. The agency said it will use the comments to decide whether it should further revise the policy.

"CMS is committed to establishing and maintaining policies in all areas of Medicare that promote efficient and appropriate use of medical interventions, protect beneficiaries and enable providers to furnish high quality care," CMS acting administrator Leslie Norwalk said in a statement.