Medicare Learning Network
MLN Matters®
CMS
Information for Medicare Fee-For-Service Health Care Professionals

MLN Matters Number: MM4135
Related Change Request (CR) #: 4135
Related CR Release Date: November 10, 2005
Effective Date: April 1, 2006
Related CR Transmittal #: 751
Implementation Date: April 3, 2006

National Monitoring Policy for EPO and Aranesp for End Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities

Note: This article was updated on February 21, 2013, to reflect current Web addresses. This article was previously revised on August 17, 2007 to add references to related articles. You should review MM5251 and MM5700 to see changes made to the national ESA monitoring policy (referred to as EMP). These may be viewed at http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/mm5251.pdf and http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/mm5700.pdf on the CMS website. All other information remains unchanged.

Provider Types Affected

Providers billing Medicare fiscal intermediaries (FIs) for services related to erythropoietin (EPO) and darbepoetin (Aranesp) for ESRD patients

Provider Action Needed

STOP – Impact to You

This article is based on Change Request (CR) 4135, in which the Centers for Medicare & Medicaid Services (CMS) institutes a new national monitoring policy for claims for erythropoietin and darbepoetin (EPO and Aranesp) administered to ESRD patients treated in renal dialysis facilities.

CAUTION – What You Need to Know

Under the new monitoring policy, CMS expects a 25 percent reduction in the dosage of these drugs for patients whose hematocrit exceeds 39.0 (hemoglobin of 13.0). If the dosage is not reduced, payment will be made for the medications as if the reduction had occurred. Also a new maximum limitation for each drug per month is created.

GO – What You Need to Do

See the *Background* section of this article for further details regarding these changes.

Background

CMS previously had an EPO monitoring policy, and its methodology limited monitoring of EPO to post-payment review based on a 90-day rolling average of claims. The CMS target for taking action was a hematocrit level of 37.5, although higher levels could be approved upon medical justification by the treating physician.

In the fall of 2003, CMS solicited scientific information from the ESRD community in order to develop a national claims monitoring policy on erythropoietin administered to ESRD patients in renal dialysis facilities. CMS found that there is considerable natural variability in individual patient hematocrit levels, making it difficult to consistently maintain a hematocrit within the narrow range of 33-36.

Therefore, effective April 1, 2006, Medicare is implementing a national monitoring policy to promote the efficient use of EPO and Aranesp in the Medicare ESRD in-facility dialysis population. To allow for unanticipated increases in hematocrit, CMS will not initiate monitoring until the hematocrit level reaches 39.0 (or a hemoglobin of 13.0).

Note: Hematocrit levels are reported in value code 49 (reflecting the most recent reading taken before the start of the billing period), while hemoglobin readings (taken before the start of the billing period) are reported in value code 48.

For claims on bill type 72X with hematocrit readings above the threshold of 39.0 (or hemoglobin of 13.0), the dosages of EPO and Aranesp should be reduced by 25 percent over the preceding month.

Example: If a beneficiary's hematocrit level taken in May is 40.0, the facility should report this number in value code 49 on the June bill. The facility should reduce the dosage of EPO furnished to the beneficiary in June by 25 percent over that provided in May; e.g., if the beneficiary was given 10,000 IU (International Unit) in May, he/she should receive 7,500 IU in June.

If the dose has been reduced by 25 percent, modifier GS should be reported on the claim. When the GS modifier appears on the claim, payment will be made based on the reported dosage.

Note: Modifier GS is defined as "Dosage of EPO or Darbepoetin Alfa has been reduced 25 percent of preceding month's dosage."

For claims on bill type 72X, with hematocrit levels above 39.0 (hemoglobin of 13.0) without modifier GS, CMS will reduce the dosage payable by 25 percent for EPO and Aranesp. For example, if the June hematocrit level is 40.0, and there is no GS modifier and the dosage is 10,000 IU, CMS will pay the claim as if the dosage had been 7,500 IU.

Note: Renal facilities may not bill Medicare beneficiaries for the payment reduction unless they have issued an Advanced Beneficiary Notice **prior** to administration of EPO or Aranesp. Medicare FIs will hold providers liable for the 25 percent reduction unless the occurrence code 32 is present on the claim or a modifier GA is present on the line item.

In addition to the dosage adjustments, effective April 1, 2006, Medicare will not make payment and will return to the provider those claims for dosage of EPO (HCPCS Q4055 (J0886 as of January 1, 2006)) in excess of 500,000 IUs per claim or Aranesp (HCPCS Q4054 (J0882 as of January 1, 2006)) in excess of 1500 mcg per claim.

Additional Information

For complete details, please see the official instruction issued to your intermediary regarding this change. That instruction may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R751CP.pdf on the CMS website.

If you have any questions, please contact your intermediary at their toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.