



Attention Renal Dialysis Facilities!

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MLN Matters Number: MM5251

Related Change Request (CR) #: 5251

Related CR Release Date: August 25, 2006

Effective Date: October 1, 2006 for new modifier definition; April 1, 2006 for method one exclusion

Related CR Transmittal #: R1043CP

Implementation Date: October 2, 2006 for new modifier definition; January 1, 2007 for method one exclusion.

Revisions to the Epoetin (EPO) and Aranesp Monitoring Policy

Note: This article was revised on August 17, 2007 to add a reference to MM5700, which made changes to the national ESA monitoring policy (referred to as EMP). The article may be viewed at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5700.pdf> on the CMS website.

Provider Types Affected

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

Background

Change Request (CR) 4135 titled, "National Monitoring Policy for Erythropoietin (EPO) and Aranesp® for End Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities," inadvertently did not exempt claims for Method 1 home dialysis patients who self-administer EPO or Aranesp®.

Consequently, some claims for home dialysis patients may receive an inappropriate 25% reduction in payment. Claims for home dialysis patients who self-administer these drugs in the home **should not** have been included in the requirements for CR 4135. Claims for patients who normally perform home dialysis and self-administration of EPO or Aranesp® and who need to receive back-up services in-facility should also be exempt.

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In addition, CR4135 announced that Medicare would not apply a 25% payment reduction on claims for EPO or Aranesp® when a GS modifier was reported on the claim. The GS modifier was defined as *“Dosage of EPO or Darbepoetin Alfa has been reduced 25% of preceding month’s dosage.”* This definition of the GS modifier precluded providers from informing Medicare when they made a dose reduction in EPO or Darbepoetin Alfa but the total billed EPO or Darbepoetin Alfa reported was not 25% less than the preceding month’s billed units.

Key Points

- CR4135 is to be applied to patients who receive their EPO or Aranesp® in the renal dialysis center.
- CR4135, effective for services furnished on or after April 1, 2006, implemented a national claims monitoring policy for EPO and Aranesp® in the Medicare ESRD in-facility dialysis population.
- For dates of service April 1, 2006, and later, claims for patients who have opted to receive home dialysis under Method 1 or Method 2 and are self-administering the EPO or Aranesp® in their home are exempt from the policy and therefore, are not subject to automatic monitoring or the automatic 25% payment reduction as described in CR 4135.
- Providers should report condition code 70 on claims to identify home dialysis patients who self-administer EPO or Aranesp® and condition code 76 for the home dialysis patients who received back-up services in the facility.
- Upon implementation of this instruction on January 1, 2007, providers may request claim adjustments for home dialysis claims that received an inappropriate 25% reduction in payment.
- Medicare requested and received a revised definition of the GS modifier to enable providers to inform Medicare when a hematocrit or hemoglobin level responsive dose reduction occurred and was maintained.
- Effective October 1, 2006, the revised definition of the GS modifier is, *“Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level.”*
- Providers should include the GS modifier on the claim when the reported hematocrit level is above 39.0% (hemoglobin 13.0g/dL) and a corresponding dose reduction was made and maintained.

Implementation

The implementation date for this instruction is October 2, 2006 for the new modifier definition; January 1, 2007 for the method one exclusion.

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Additional Information

If you have questions, please contact your Medicare FI, at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

For complete details, please see the official instruction issued to your FI regarding this change. The revised coverage rules for EPO are explained in the *Medicare Benefit Policy Manual*, Chapter 11, Section 60.4, which is included in the official instruction attachment. That instruction may be viewed by going to <http://www.cms.hhs.gov/Transmittals/downloads/R1043CP.pdf> on the CMS website.

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