



Related MLN Matters Article #: MM5700

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Modification to the National Monitoring Policy for Erythropoiesis Stimulating Agents (ESAs) for End-Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities

Key Words

MM5700, CR5700, R1307CP, Monitoring, ESAs, ESRD, Renal, Dialysis

Provider Types Affected

Renal dialysis facilities billing Medicare Fiscal Intermediaries (FIs) and/or Part A/B Medicare Administrative Contractors (A/B MACs) for services related to erythropoietin (EPO) and Darbepoetin Alfa (Aranesp®) for Medicare ESRD beneficiaries

Key Points

- The effective date of the instruction is January 1, 2008.
- The implementation date is January 7, 2008.
- In 2003, the Centers for Medicare & Medicaid Services (CMS) solicited input from the ESRD community in order to develop a national claims monitoring policy for ESAs that are administered to ESRD patients receiving dialysis in a renal dialysis facility.
- After considerable input from the ESRD community, CMS implemented the first iteration of the national ESA monitoring policy (EMP) effective for dates of service on or after April 1, 2006.
- Emerging scientific data on the use of ESAs has prompted CMS to revise the EMP to further control over-utilization and inappropriately sustained high hematocrit or hemoglobin levels.
- Change Request (CR) 5700 makes the following changes that will be effective for dates of service on or after January 1, 2008:
 - Requests for payments or claims for type of bill (TOB) 72X for ESAs (Healthcare Common Procedure Coding System (HCPCS) Q4081, Epogen®; J0882, Aranesp®) for ESRD patients that received dialysis in renal dialysis facilities and reported a hematocrit level (value code 49) exceeding 39.0% (or hemoglobin (value code 48) exceeding 13.0g/dL) for 3 or more consecutive billing cycles, immediately prior to and including the current billing cycle, will have the reported dosage reduced by 50% on which payment may be made.

- Such claims should report HCPCS Q4081/J0882 on the line item with modifiers:
 - ED (Hematocrit greater than 39.0% or hemoglobin greater than 13.0g/dL for 3 or more consecutive billing cycles immediately prior to and including the current billing cycle) or
 - EE (Hematocrit greater than 39.0% or hemoglobin greater than 13.0g/dL for less than 3 consecutive billing cycles immediately prior to and including the current billing cycle).
- Providers may continue to report the GS modifier (Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level) when the reported hematocrit or hemoglobin levels exceed the monitoring threshold and a dose reduction has occurred.
- When the GS modifier is included on claims reporting modifier EE and HCPCS Q4081/J0882 on the line, the claim will be paid in full. The GS modifier, however, will have no effect on the 50% reduction of the reported dose on which payment may be made on claims reporting modifier ED and HCPCS Q4081/J0882 line items.
- TOB 72X claims reporting hematocrit greater than 39.0% or hemoglobin greater than 13.0g/dL with HCPCS Q4081/J0882 on the line will be returned to provider if neither modifier ED or EE are present on at least one of the line items, or if both modifiers ED and EE are present.
- When Medicare makes a reported dosage reduction, the remittance advice will contain reason code 153 (Payment adjusted because the payer deems the information submitted does not support this dosage).
- The dosage reduction may be taken by reducing covered units on the claim or by reducing the total payment applicable to the line.
- Medicare systems shall continue to allow for medical review override of these payment reductions.
- The medically unlikely edit (MUE) threshold has been revised. The MUE for claims for Epogen® (Q4081) is reduced from 500,000 to 400,000 units, and from 1500 units to 1200 units for Aranesp® (J0882). Claims reporting doses exceeding the new thresholds are assumed to have typographical errors and will be returned to providers for correction.
- ESA claims for ESRD patients who receive their dialysis at home and self-administer their ESAs are exempt from this policy as reported in the earlier MLN Matters articles MM4135 and MM5251 (See the Important Links section below.).
- None of the above requirements are applicable to 72X claims containing condition code 70 or 76 and Method I or II is applicable to the billing cycle.
- The chart on page 3 of MM5700 illustrates the resultant claim actions under all possible reporting scenarios.

Important Links

The related MLN Matters article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5700.pdf> on the CMS website.

The official instruction (CR5700) regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1307CP.pdf> on the CMS website.

Providers may want to review earlier articles:

- MM4135: National Monitoring Policy for EPO and Aranesp for End Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4135.pdf>) and
- MM5251: Revisions to the Epoetin (EPO) and Aranesp Monitoring Policy (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5251.pdf>) on the CMS website.

Providers with questions may contact their Medicare FI or A/B MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.