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Implementation Date: January 7, 2008

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

### Provider Types Affected

Renal dialysis facilities billing Medicare fiscal intermediaries (FIs) and/or A/B Medicare administrative contractors (A/B MACs) for services related to erythropoietin (EPO) and darbepoetin (Aranesp) for Medicare ESRD beneficiaries.

### Background

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 erythropoiesis stimulating agents, also referred to as ESAs, 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 referred to as EMP, effective for dates of service on or after April 1, 2006. (See earlier articles related to the EMP at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4135.pdf> and <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5251.pdf> on the CMS website.)

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Emerging scientific data on the use of ESAs has prompted CMS to again revise the EMP to further control over-utilization and inappropriately sustained high hematocrit or hemoglobin levels.

## What You Need to Know

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CR 5700 makes the following changes effective for dates of service on or after January 1, 2008

- Requests for payments or claims for 72X TOBs for ESAs (HCPCS Q4081, Epogen®, J0882 Aranesp®) for ESRD patients receiving dialysis in renal dialysis facilities and reporting 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 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) with HCPCS Q4081/J0882 on the line.
- 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 J0882/Q4081 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 J0882/Q4081 line items.
- 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 ED 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.

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- 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 to 400,000 units from 500,000, and to 1200 units from 1500 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 referenced above.
- 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 following chart below illustrates the resultant claim actions under all possible reporting scenarios.

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	ED Modifier? (Hct >39.0% or Hgb >13.0g ≥3 cycles)	EE Modifier? (Hct >39.0% or Hgb >13.0g <3 cycles)	GS Modifier? (Dosage reduced and maintained)	Claim Action
No	N/A	N/A	N/A	Do not reduce reported dose.
Yes	No	No	No	Return to provider for correction. Claim must report either ED or EE.
Yes	No	No	Yes	Return to provider for correction. Claim must report either ED or EE.
Yes	No	Yes	Yes	Do not reduce reported dose.
Yes	No	Yes	No	Reduce reported dose 25%.
Yes	Yes	No	Yes	Reduce reported dose 50%.
Yes	Yes	No	No	Reduce reported dose 50%.

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## Additional Information

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For complete details regarding these changes please see the official instruction (CR5700) issued to your Medicare FI or A/B MAC. That instruction is at <http://www.cms.hhs.gov/Transmittals/downloads/R1307CP.pdf> on the CMS website.

If you have questions, please contact your 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.

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