CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1307	**Date: JULY 20, 2007**
	Change Request 5700

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

I. SUMMARY OF CHANGES: This CR broadens the application of the national monitoring policy to include all drugs catagorized as erythropoietic stimulating agents (ESAs). Future CRs will be issued to provide additional instructions as new drugs enter the market. This CR reduces the medically unbelievable edit threshold described in CRs 4135/5251 to 400,000 units from 500,000 for Epogen and to 1200 mcg from 1500 for Aranesp. It also instructs systems to apply a 50 percent reduction to the reported dose on ESA claims for ESRD patients receiving their dialysis in renal dialysis facilities when the hematocrit has been above 39.0 percent (or hemoglobin above 13.0g/dL) for 3 or more consecutive billing cycles immediately prior to and including the current billing cycle. As intended in CRs 4135/5251, this policy does not apply to ESA claims for patients who receive their dialysis at home and self-administer their ESAs.

New / Revised Material
Effective Date: January 1, 2008
Implementation Date: January 7, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	8/60/4/Epoetin Alfa
R	8/60/7/Darbepoetin Alfa (Aranesp) for ESRD patients

III. FUNDING:
No budget implications.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1307	Date: July 20, 2007	Change Request: 5700

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

Effective Date: January 1, 2008

Implementation Date: January 7, 2008

I. GENERAL INFORMATION

A. Background: In fall 2003, the Centers for Medicare & Medicaid Services (CMS) solicited input from the end-stage renal disease (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 the EMP, effective for dates of service April 1, 2006, and later (change request (CR) 4135 dated November 10, 2005). This version instructed Medicare contractors to make payments based on a 25% reduction in the reported ESA dose on the claim when the hematocrit level exceeded 39.0% (or hemoglobin exceeded 13.0g/dL) unless the provider indicated, by appending a GS modifier to the claim, that the amount of ESA on the claim reflected a 25% dose reduction compared to the prior month. A medically unbelievable edit (MUE) was implemented for claims for Epoetin Alfa (EPO) over 500,000 units and Darbepoetin Alfa (Aranesp®) over 1500 micrograms in the billed month. Since amounts exceeding the MUE were assumed to be typographical errors, claims reporting amounts above the threshold were returned to providers for correction.

CR 5251, issued August 25, 2006, revised the national monitoring policy. In essence, the revision clarified claims processing systems instructions contained in CR 4135 for patients that receive home dialysis, and specified that effective for claims with dates of service on or after April 1, 2006, patients that opt to receive home dialysis are not subject to the 25% dose reduction and are not required to report the GS modifier. The CR also redefined the GS modifier to indicate that the ESA dose had been reduced and maintained in response to high hematocrit or hemoglobin levels, without specifying the percentage of the reduction or when it occurred, effective for claims with dates of service on or after October 1, 2006.

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.

B. Policy: Effective for dates of service on or after January 1, 2008, for requests for payments or claims for ESAs for ESRD patients receiving dialysis in renal dialysis facilities and reporting a hematocrit level exceeding 39.0% (or hemoglobin exceeding 13.0g/dL) for 3 or more consecutive billing cycles immediately prior to and including the current billing cycle, the dosage payable shall be reduced by 50%, based on the reported dose. In addition, claims must report modifiers ED or EE for hematocrit exceeding 39.0% or hemoglobin exceeding 13.0g/dL. Providers may continue to report the GS modifier 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, the claim will be paid in full. The GS modifier, however, will have no effect on the 50% dosage reduction, or claims reporting modifier ED. Claims must include either the ED or EE modifier if hematocrit exceeds 39.0% or hemoglobin exceeds 13.0g/dL. Claims with neither modifier or with both modifiers will be returned to the provider for correction.

In addition, the medically unbelievable edit (MUE) threshold has been revised. The MUE for claims for Epogen® is reduced to 400,000 units from 500,000, and to 1200 micrograms from 1500 micrograms for Aranesp®. Claims reporting doses exceeding the new thresholds are assumed to have typographical errors and will be returned to providers for correction.

As intended in CR 4135 and further clarified in CR 5251, this policy does not apply to ESA claims for ESRD patients who receive their dialysis at home and self-administer their ESA.

Below is a chart illustrating 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%.

Modifier Definitions:
*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
*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
*GS: Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	**Requirement**	**Responsibility (place an "X" in each applicable column)**										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5700.1	Medicare systems shall not apply any of the requirements in this instruction to 72x claims when							X				

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	condition code 70 or 76 is present on the claim and a method 1 or 2 selection is applicable to the billing period.											
5700.2	Medicare systems shall return to provider 72x claims with dates of service on or after January 1, 2008, that report a value 48 exceeding 13.0 with a line item HCPCS present of Q4081 or J0882 when modifier ED or EE is not present on at least one of the line items.							X				
5700.3	Medicare systems shall return to provider 72x claims with dates of service on or after January 1, 2008, that report a value 49 exceeding 39.0 with a line item HCPCS present of Q4081 or J0882 when modifier ED or EE is not present on at least one of the line items.							X				
5700.4	Medicare systems shall return to provider 72x claims that contain both modifiers EE and ED.							X				
5700.5	When value code 49 exceeds 39.00 or value code 48 exceeds 13.00, Medicare systems shall apply a 50% reduction to the covered units on line items with HCPCS J0882 or Q4081 containing modifier ED (regardless if modifier GS is present or not).							X				
5700.5.1	Medicare systems shall hold the provider liable for the 50% reduction.							X				
5700.5.2	Medicare systems shall notify providers of reduction with reason code 153 – Payment adjusted because the payer deems the information submitted does not support this dosage.							X				
5700.5.3	Medicare systems shall notify beneficiaries of the reduction in dosage eligible for payment with MSN code 15.15 – Payment has been reduced because information provided does not support the need for this item as billed. This is a set MSN message that cannot be changed. It aligns with the reason code above.							X				
5700.6	When value code 49 exceeds 39.00 or value code 48 exceeds 13.00, Medicare systems shall apply a 25% reduction to the covered units on line items with HCPCS J0882 and Q4081 when modifier EE is reported without a modifier GS on the line.							X				
5700.7	When value code 49 exceeds 39.00 or value code 48 exceeds 13.00, Medicare systems shall not apply a reduction to the covered units on line items with							X				

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	HCPCS J0882 and Q4081 when modifier EE is reported with modifier GS on the line.											
5700.8	Medicare systems shall reduce the medically unbelievable edit (MUE) for Epogen® (Q4081) to 400,000 units effective for claims with dates of service on or after January 1, 2008.							X				
5700.9	Medicare systems shall reduce the MUE for Aranesp® (J0882) to 1200 units effective for claims with dates of service on or after January 1, 2008.							X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5700.10	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X								

IV. SUPPORTING INFORMATION

5700.5 & 5700.6	The reduction may be taken by reducing covered units on the claim or by reducing the total payment applicable to the line.							X				
5700.5 & 5700.6	Medicare systems shall continue to allow for medical review override of the payment reductions associated with this policy.							X				

V. CONTACTS

Pre-Implementation Contact(s): Maria Ciccanti, Coverage, maria.ciccanti@cms.hhs.gov, 410-786-3107, Pat Brocato-Simons, Coverage, patricia.brocatosimons@cms.hhs.gov, 410-786-0261, Wendy Tucker, Institutional Claims Processing, wendy.tucker@cms.hhs.gov, 410-786-3004

Post-Implementation Contact(s): Appropriate CMS Regional Office

VI. FUNDING

A. ***For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC)*****:**
No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2008 operating budgets.

B. ***For Medicare Administrative Contractors (MAC)*****:**
The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

60.4 - Epoetin Alfa (EPO)

(Rev.1307, Issued: 07-20-07, Effective: 01-01-08, Implementation: 01-07-08)

Coverage rules for Epoetin Alfa (EPO) are explained in the Medicare Benefit Policy Manual, *Publication 100-02,* chapter 11. For an explanation of Method I and Method II reimbursement for patients dialyzing at home, see §40.1.

Fiscal intermediaries (FIs) pay for EPO to end-stage renal disease (ESRD) facilities as a separately billable drug to the composite rate. No additional payment is made to administer EPO, whether in a facility or a home. Effective January 1, 2005, the cost of supplies to administer EPO may be billed to the FI. HCPCS A4657 and Revenue Code 270 should be used to capture the charges for syringes used in the administration of EPO.

If the beneficiary obtains EPO from a supplier for self-administration, the supplier bills the durable medical equipment regional carrier (DMERC) and the DMERC pays at the rate shown in §60.4.3

Program payment may not be made to a physician for EPO for self-administration. Where EPO is furnished by a physician payable as "incident to services" the carrier processes the claim.

EPO Payment Methodology

Type of Provider	Separately Billable	DMERC Payment	No payment
In-facility freestanding and hospital-based ESRD facility	X		
Self-administer Home Method I	X		
Self-administer Home Method II		X	
Incident to physician in facility or for self-administration *			X

Medicare pays for a drug if self-administered by a dialysis patient. When EPO is administered in a renal facility, the service is not an "incident to" service and not under the "incident to" provision.

Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48. See §60.4.1.

Effective for services provided on or after April 1, 2006, Medicare has implemented a national claims monitoring policy for EPO administered in Medicare renal dialysis facilities. *This policy does not apply to claims for EPO for patients who receive their dialysis at home and self-administer their EPO.*

While Medicare is not changing its coverage policy on erythropoietin use to maintain a target hematocrit level between 30% and 36%, we believe the variability in response to EPO warrants postponing requiring monitoring until the hematocrit reaches higher levels. For dates of services April 1, 2006, and later, *the Centers for Medicare & Medicaid Services (*CMS) will not *initiate* monitoring until the hematocrit level *exceeds* 39.0*%* or *the* hemoglobin *level exceeds* 13.0g/dL. This does not preclude the contractors from performing medical review at lower levels. *The Food and Drug Administration (FDA) labeling for EPO notes that as the hematocrit approaches a reading of 36.0 (or hemoglobin 12.0g/dL), the dose of the drug should be reduced by 25%.*

Effective for services provided on or after April 1, 2006, for claims reporting hematocrit or hemoglobin levels exceeding the monitoring threshold, the dose shall be reduced by 25% over the preceding month. Providers may report that a dose reduction did occur in response to the reported elevated hematocrit or hemoglobin level by adding a GS modifier on the claim. The definition of the GS modifier continues to be defined as: "Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level." Thus, for claims reporting a hematocrit level or hemoglobin level exceeding the monitoring threshold without the GS modifier, CMS will reduce the dosage reported on the claim by 25%. The excess dosage is considered to be not reasonable and necessary. Providers are reminded that the patient's medical records should reflect hematocrit/hemoglobin levels and any dosage reduction reported on the claim during the same time period for which the claim is submitted.

Effective for dates of service provided on and after January 1, 2008, requests for payments or claims for EPO for ESRD patients receiving dialysis in renal dialysis facilities reporting a hematocrit level exceeding 39.0% (or hemoglobin exceeding 13.0g/dL) shall also include modifier ED ***or*** *EE. Claims reporting neither modifier or both modifiers will be returned to the provider for correction.*

The definition of modifier ED is "The hematocrit level has exceeded 39.0% (or hemoglobin 1evel has exceeded 13.0g/dL) 3 or more consecutive billing cycles immediately prior to and including the current billing cycle." The definition of modifier EE is "The hematocrit level has exceeded 39.0% (or hemoglobin level has exceeded 13.0g/dL) less than 3 consecutive billing cycles immediately prior to and including the current billing cycle." The GS modifier continues to be defined as stated above.

Providers may continue to report the GS modifier when the reported hematocrit or hemoglobin levels exceed the monitoring threshold for less than 3 months and a dose reduction has occurred. When both modifiers GS and EE are included, no reduction in the reported dose will occur. Claims reporting a hematocrit or hemoglobin level exceeding the monitoring threshold and the ED modifier shall have an automatic 50% reduction in the reported dose applied, even if the claim also reports the GS modifier.

Below is a chart illustrating the resultant claim actions under all possible reporting scenarios:

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	*ED Modifier? (Hct >39% or Hgb >13g/dL ≥3 cycles)*	*EE Modifier? (Hct >39% or Hgb >13g/dL <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%.*

In addition, for dates of service on and after January 1, 2008, CMS will implement a revised medically unbelievable edit (MUE). For dates of service on and after January 1, 2008, the MUE for claims for Epogen® is reduced to 400,000 units from 500,000. It is likely that claims reporting doses exceeding the new threshold reflect typographical errors and will be returned to providers for correction.

In some cases, physicians may believe there is medical justification to maintain a hematocrit above 39.0*% or hemoglobin above 13.0g/dL.* Beneficiaries, physicians, and/or renal facilities may submit additional medical documentation to justify this belief under the routine appeal process. You may reinstate any dosage reduction amounts under this first level appeal process when you believe the documentation supports a higher hematocrit/hemoglobin level.

Providers are reminded that, *in accordance with FDA labeling*, CMS expects that as the hematocrit approaches 36.0% (hemoglobin 12.0g/dL), a dosage reduction occurs. Providers are expected to maintain hematocrit levels between 30.0 to 36.0% (hemoglobin 10.0-12.0g/dL). Hematocrit levels that remain below 30.0% (hemoglobin levels below 10.0g/dL)) despite dosage increases, should have causative factors evaluated. The patient's medical record should reflect the clinical reason for dose changes and hematocrit levels outside the range of 30.0-36.0% (hemoglobin levels 10.0-12.0g/dL). Medicare contractors may review medical records to assure appropriate dose reductions are applied and maintained and hematological target ranges are maintained.

These hematocrit requirements apply only to EPO furnished as an ESRD benefit under §1881(b) of the Social Security Act. EPO furnished incident to a physician's service is

not included in this policy. Carriers have discretion for local policy for EPO furnished as "incident to service."

60.7 – Darbepoetin Alfa (Aranesp®) for End-Stage Renal Disease (ESRD) Patients

(Rev.1307, Issued: 07-20-07, Effective: 01-01-08, Implementation: 01-07-08

Coverage rules for Aranesp® are explained in the Medicare Benefit Policy Manual, *Publication 100-02*, chapter 11. For an explanation of Method I and Method II reimbursement for patients dialyzing at home see §40.1.

Fiscal intermediaries (FIs) pay for Aranesp® to end-stage renal disease (ESRD) facilities as a separately billable drug to the composite rate. No additional payment is made to administer Aranesp®, whether in a facility or a home. Effective January 1, 2005, the cost of supplies to administer Aranesp® may be billed to the FI. HCPCS A4657 and Revenue Code 270 should be used to capture the charges for syringes used in the administration of Aranesp®.

If the beneficiary obtains Aranesp® from a supplier for self-administration, the supplier bills the durable medical equipment regional carrier (DMERC), and the DMERC pays in accordance with MMA Drug Payment Limits Pricing File.

Program payment may not be made to a physician for self-administration of Aranesp®. When Aranesp® is furnished by a physician as "incident to services," the carrier processes the claim.

For ESRD patients on maintenance dialysis treated in a physician's office, code *J0882,* "injection, darbepoetin alfa, 1 mcg (for ESRD patients)," should continue to be used with the hematocrit included on the claim. (For ANSI 837 transactions, the hematocrit (HCT) value is reported in 2400 MEA03 with a qualifier of R2 in 2400 MEA02.) Claims without this information will be denied due to lack of documentation. Physicians who provide Aranesp® for ESRD patients on maintenance dialysis must bill using code *J0882*.

Darbepoetin Alfa Payment Methodology

Type of Provider	Separately Billable	DMERC Payment	No Payment
In-facility freestanding and Hospital-based ESRD facility	X		
Self-administer Home Method I	X		
Self-administer Home Method II		X	
Incident to physician in facility or for self-administration *			X

Medicare pays for a drug if self-administered by a dialysis patient. When Aranesp® is administered in a dialysis facility, the service is not an "incident to" service, and not under the "incident to" provision.

Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48. See §60.4.1.

Effective for services provided on or after April 1, 2006, Medicare has implemented a national claims monitoring policy for Aranesp® administered in Medicare renal dialysis facilities. *This policy does not apply to claims for Aranesp® for patients who receive their dialysis at home and self-administer their Aranesp®.*

While Medicare is not changing its coverage policy on erythropoietin use to maintain a target hematocrit level between 30% and 36%, we believe the variability in response to EPO warrants postponing requiring monitoring until the hematocrit reaches higher levels. For dates of services on and after April 1, 2006, the Centers for Medicare & Medicaid Services (CMS) will not initiate monitoring until the hematocrit level exceeds 39.0% or the hemoglobin level exceeds 13.0g/dL. This does not preclude the contractors from performing medical review at lower levels. The Food and Drug Administration (FDA) labeling for Aranesp® notes that as the hematocrit approaches a reading of 36.0% (or hemoglobin 12.0g/dL), the dose of the drug should be reduced by 25%.

Effective for dates of service provided on or after April 1, 2006, for claims reporting hematocrit or hemoglobin levels exceeding the monitoring threshold, the dose shall be reduced by 25% over the preceding month. Providers may report that a dose reduction did occur in response to the reported elevated hematocrit or hemoglobin level by adding a GS modifier on the claim. The definition of the GS modifier continues to be defined as: "Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level." Thus, for claims reporting a hematocrit level or hemoglobin level exceeding the monitoring threshold without the GS modifier, CMS shall reduce the dosage reported on the claim by 25%. The excess dosage is considered to be not reasonable and necessary. Providers are reminded that the patient's medical records should reflect hematocrit/hemoglobin levels and any dosage reduction reported on the claim during the same time period for which the claim is submitted.

*Effective for dates of service provided on an after January 1, 2008, requests for payments or claims for Aranesp® for ESRD patients receiving dialysis in renal dialysis facilities reporting a hematocrit level exceeding 39.0% (or hemoglobin exceeding 13.0g/dL) shall also include modifier ED **or** EE. Claims reporting neither modifier or both modifiers will be returned to the provider for correction.*

The definition of modifier ED is "The hematocrit level has exceeded 39.0% (or hemoglobin 1evel has exceeded 13.0g/dL) 3 or more consecutive billing cycles immediately prior to and including the current billing cycle." The definition of modifier EE is "The hematocrit level has exceeded 39.0% (or hemoglobin level has exceeded

13.0g/dL) less than 3 consecutive billing cycles immediately prior to and including the current billing cycle." The GS modifier continues to be defined as stated above.

Providers may continue to report the GS modifier when the reported hematocrit or hemoglobin levels exceed the monitoring threshold for less than 3 months and a dose reduction has occurred. When both modifiers GS and EE are included, no reduction in the reported dose will occur. Claims reporting a hematocrit or hemoglobin level exceeding the monitoring threshold and the ED modifier shall have an automatic 50% reduction in the reported dose applied, even if the claim also reports the GS modifier.

Below is a chart illustrating the resultant claim actions under all possible reporting scenarios.

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	***ED Modifier? (Hct >39% or Hgb >13g/dL ≥3 cycles)***	***EE Modifier? (Hct >39% or Hgb >13g/dL <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%.*

In addition, for dates of service on and after January 1, 2008, CMS will implement a revised medically unbelievable edit (MUE). For dates of service on and after January 1, 2008, the MUE for claims for Aranesp® is reduced to 1200 mcg from 1500 mcg. It is likely that claims reporting doses exceeding the new threshold reflect typographical errors and will be returned to providers for correction.

In some cases, physicians may believe there is medical justification to maintain a hematocrit above 39.0% or hemoglobin above 13.0g/dL. Beneficiaries, physicians, and/or renal facilities may submit additional medical documentation to justify this belief under the routine appeal process. You may reinstate any *dosage* reduction amounts under this first level appeal process when you believe the documentation supports a higher hematocrit/hemoglobin level.

Providers are reminded that*, in accordance with FDA labeling*, CMS expects that as the hematocrit approaches 36.0% (hemoglobin 12.0g/dL), a dosage reduction occurs.

Providers are expected to maintain hematocrit levels between 30.0 to 36.0% (hemoglobin 10.0-12.0g/dL). Hematocrit levels that remain below 30.0% (hemoglobin levels below10.0g/dL) despite dosage increases, should have causative factors evaluated. The patient's medical record should reflect the clinical reason for dose changes and hematocrit levels outside the range of 30.0-36.0% (hemoglobin levels 10.0-12.0g/dL). Medicare contractors may review medical records to assure appropriate dose reductions are applied and maintained and hematological target ranges are maintained.

These hematocrit requirements apply only to Aranesp® furnished as an ESRD benefit under §1881(b) of the Social Security Act. Aranesp® furnished incident to a physician's service is not included in this policy. Carriers have discretion for local policy for Aranesp® furnished as "incident to service."