CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1043	**Date: AUGUST 25, 2006**
	Change Request 5251

Subject: Revisions to the EPO/ Aranesp Monitoring Policy

I. SUMMARY OF CHANGES: Change Request 4135 titled, National Monitoring Policy for EPO and Aranesp for End Stage Renal Disease (ESRD) Patients Treated In Renal Dialysis Facilities, instructed the Medicare system to 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 monthýs dosage." The definition of the GS modifier has been revised since the implementation of CR 4135. In addition, change request 4135 announced that the policy did not apply to patients who elect to receive their dialysis at home; however, change request 4135 did not instruct system maintainers to exempt claims for patients who elect to receive their dialysis at home.

This CR notifies contractors and providers that the the GS modifier definition is revised and instructs system maintainers to exempt claims from patients that receive their dialysis at home.

New / Revised Material
Effective Date: October 1, 2006
Implementation Date: October 2, 2006

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 additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instructions

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1043	Date: August 25, 2006	Change Request 5251

SUBJECT: Revisions to the Epoetin (EPO) and Aranesp Monitoring Policy

I. GENERAL INFORMATION

A. Background: Change Request 4135 titled, National Monitoring Policy for Erythropoietin (EPO) and Aranesp® for End Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities, did not instruct the Medicare system to exempt claims for method 1 home dialysis patients that 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 that self-administer these drugs in the home should not have been included in the requirements for CR 4135. Claims for patients that normally perform home dialysis and self-administration of EPO or Aranesp® that have a need to receive back-up services in-facility should also be exempt.

In addition, change request 4135 instructed the Medicare system to 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.

B. Policy: Change Request 4135 is to be applied to patients that receive their EPO or Aranesp® in the renal dialysis center. For dates of service April 1, 2006 and later, claims for patients that have opted to receive home dialysis under method 1 or method 2 and are self-administering the EPO or Aranesp® in their home are not required to report the GS modifier and therefore, are not subject to the 25% payment reduction as described in CR 4135. Providers should report condition code 70 on claims to identify home dialysis patients that self-administer EPO or Aranesp® and condition code 76 for the home dialysis patients that received back-up services in the facility. Upon implementation of this instruction, providers may request claim adjustments for home dialysis claims that received an inappropriate 25% reduction in payment.

Change Request 4135, 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. Medicare requested and received a revised definition of the GS modifier to enable providers to inform Medicare when they reduced the dosage of EPO or Darbepoetin Alfa in response to a hematocrit or hemoglobin level. 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.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5251.1	Effective for dates of service October 1, 2006, and later, contractors shall be aware of the revised definition of the GS modifier, "Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level."	X								
5251.2	Medicare systems shall not apply the 25% reduction in EPO payment to bill type 72x when condition code 70 or 76 is present on the claim and a method 1 selection is applicable to the billing period for dates of service April 1, 2006, and later.					X				
5251.3	Medicare systems shall not apply the 25% reduction in Aranesp® payment (HCPCS J0882) to bill type 72x when condition code 70 or 76 is present on the claim and a method 1 selection is applicable to the billing period for dates of service April 1, 2006, and later.					X				
5251.4	Medicare systems shall not apply the EPO and Aranesp® Monitoring Policy medically unbelievable edits to 72x claims with a condition code 70 or 76 present and a method one selection is applicable to the billing period for dates of service April 1, 2006, and later.					X				
5251.5	Medicare contractors shall adjust 72x claims with a condition code 70 or 76 present and a valid method one selection that received an incorrect 25% reduction in payment for EPO or Aranesp® when brought to their attention within 6 months of implementation.	X								
5251.6	Medicare systems shall allow payment of Aranesp® when either a hemoglobin (value code 48) or hematocrit (value code 49) is reported on claims with dates of service on or after April 1, 2006.	X				X				

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5251.7	Medicare systems shall allow a medical review bypass of the 25% payment reduction when overturned on appeal for claims with dates of service on or after April 1, 2006.	X				X				

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5251.8	A provider education article related to this instruction will be available at 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 and incorporated into any educational events on this topic. 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								

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: 5251.1 is effective for dates of service October 1, 2006, and later. 5251.2 thru 5251.7 are effective for dates of service April 1, 2006, and later. **Implementation Date:** Implementation date for 5251.1 is October 2, 2006. Implementation date for 5251.2 thru 5251.7 is January 2, 2007. **Pre-Implementation Contact(s):** EPO Monitoring Policy – Maria Ciccanti 410-786-3107 Claims Processing - Wendy Tucker 410-786-3004 **Post-Implementation Contact(s):** Appropriate RO	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

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

60.4 - Epoetin Alfa (EPO)

(Rev. 1043, Issued: 08-25-06, Effective: 10-01-06, Implementation: 10-02-06)

Coverage rules for EPO are explained in the Medicare Benefit Policy Manual, 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*.

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,* CMS will not require contractors to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). *This does not preclude the contractors from performing medical review at lower levels.* The Food and Drug Administration labeling for EPO notes that as the hematocrit approaches a reading of 36, the dose of the drug should be reduced by 25%.

For dates of service April 1, 2006 through September 30, 2006, claims with hematocrit readings above the threshold of 39.0 (or hemoglobin above 13.0), the dose should be reduced by 25% over the preceding month. For example, if the 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 in June 25% over that provided in May. For example, if the patient was given 10,000 IUs in May, they should receive 7,500 IUs in June.

If the dose has been reduced by 25%, dialysis facilities report modifier GS on the claim. *For dates of service April 1, 2006 through September 30, 2006,* modifier GS is defined as "Dosage of EPO or Darbepoetin Alfa has been reduced by 25% of preceding month's dosage." Renal dialysis facilities generally bill monthly for all dialysis related services. However, facilities may infrequently encounter a situation where the patient was absent from the facility for a significant portion of the month. In such cases, the facility may use the GS modifier on the claim if the average dosage of EPO for the number of days of treatment in the current month was reduced by 25% from the average dosage for the number of days the patient was treated in the previous month.

When the GS modifier appears on the claim, make payment based on the reported dosage.

For claims with hematocrit levels above 39.0 (hemoglobin above 13.0) without modifier GS, reduce the dosage payable by 25% of that reported on the claim. For example, if the June hematocrit level is 40.0 and there is no GS modifier and the dosage is 10,000 IUs, pay the claim as if the dosage had been 7,500 IUs. The excess dosage is considered to be not reasonable and necessary. As such, renal facilities may not bill Medicare beneficiaries for the payment reduction unless they have issued an Advance Beneficiary Notice prior to administration of the drug.

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

Effective October 1, 2006, the GS modifier definition is revised. The revised GS modifier definition is, "Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level." For dates of service October 1, 2006 and later providers may report the GS modifier on in-facility claims when the dose of EPO was reduced and maintained in response to a hematocrit or hemoglobin level. For dates of service October 1, 2006 and later, a claim reporting a GS modifier and a hematocrit

above 39.0 (hemoglobin 13.0) will not have an automated 25% payment reduction applied. Certain situations may occur where a hematocrit/hemoglobin responsive dose reduction of EPO occurred during one part of the billing cycle, but because of various reasons, the dose was increased another part of the billing cycle. An example is when a patient missed treatments shortly after the dose was reduced and then returned to the dialysis facility late in the billing cycle with a low hematocrit/hemoglobin level. Providers may include the GS modifier on the claim for these situations. Providers are reminded that 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 10.0-13.0g/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.

Do not make payment for dosage of EPO in excess of 500,000 IUs per month. If dosage exceeds 500,000, return the claim to the provider as a medically unbelievable error. It is more likely that claims with this volume of EPO reflect typographical errors rather than actual dosage of EPO.

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 ESRD Patients

(Rev. 1043, Issued: 08-25-06, Effective: 10-01-06, Implementation: 10-02-06)

Coverage rules for Aranesp® are explained in the Medicare Benefit Policy Manual, Chapter 11. For an explanation 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 Q4054, "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 Q4054.

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*.

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 Aranesp® warrants postponing *requiring* monitoring until the hematocrit reaches higher levels. For dates of services *April 1, 2006 and later,* CMS will not require contractors to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). *This does not preclude the contractors from performing medical review at lower levels*.

For dates of services *April 1, 2006 through September 30, 2006,* claims with hematocrit readings above the threshold of 39.0 (or hemoglobin above 13.0), the dose should be reduced by 25% over the preceding month. For example, if the 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 Aranesp® furnished in June by 25% over that provided in May. For example, if the patient was given 400 mcg in May, they should receive 300 mcg in June.

If the dose has been reduced by 25%, dialysis facilities report modifier GS on the claim. *For dates of service April 1, 2006 through September 30, 2006,* modifier GS is defined as "Dosage of EPO or Darbepoetin Alfa has been reduced 25% of preceding month's dosage." Renal dialysis facilities generally bill monthly for all dialysis related services. However, facilities may infrequently encounter a situation where the patient was absent from the facility for a significant portion of the month. In such cases, the facility may use the GS modifier on the claim if the average dosage of Aranesp® for the number of days of treatment in the current month was reduced by 25% from the average dosage for the number of days the patient was treated in the previous month.

When the GS modifier appears on the claim, make payment based on the reported dosage.

For claims with hematocrit levels above 39.0 (hemoglobin above 13.0) without modifier GS, reduce the dosage payable by 25% of that reported on the claim. For example, if the June hematocrit level is 40.0 and there is no GS modifier and the dosage is 400 mcg, pay the claim as if the dosage had been 300. The excess dosage is considered to be not reasonable and necessary. As such, renal facilities may not bill Medicare beneficiaries for the payment reduction unless they have issued an Advance Beneficiary Notice prior to administration of the drug.

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

Effective October 1, 2006, the GS modifier definition is revised. The revised GS modifier definition is, "Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level." For dates of service October 1, 2006 and later, providers may report the GS modifier on in-facility claims when the dose Darbepoetin Alfa was reduced and maintained in response to a hematocrit or hemoglobin level. For dates of service October 1, 2006 and later, a claim reporting a GS modifier and a hematocrit above 39.0 (hemoglobin 13.0) will not have an automated 25% payment reduction applied. Certain situations may occur where a hematocrit/hemoglobin responsive dose reduction of Darbepoetin Alfa occurred during one part of the billing cycle, but because of various reasons, the dose was increased another part of the billing cycle. An example is when a patient missed treatments shortly after the dose was reduced and then returned to the dialysis facility late in the billing cycle with a low hematocrit/hemoglobin level. Providers may include the GS modifier on the claim for these situations. Providers are reminded that 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 10.0-13.0g/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.

Do not make payment for dosage of Aranesp® in excess of 1500 mcg per month. If dosage exceeds 1500, return the claim to the provider as a medically unbelievable error. It is more likely that claims with this volume of Aranesp® reflect typographical errors rather than actual dosage of Aranesp®.

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."