CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 751

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: NOVEMBER 10, 2005

Change Request 4135

SUBJECT: National Monitoring Policy for EPO and Aranesp for End Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities

I. SUMMARY OF CHANGES: Medicare is instituting a new national monitoring policy for claims for erythropoietin and darbepoetin (EPO and Aranesp) for ESRD patients treated in renal dialysis facilities. Under the new monitoring policy, Medicare expects a 25 percent reduction in the dosage of the drug for patients whose hematocrit exceeds 39.0 (hemoglobin of 13.0). If the dosage is not reduced, payment will be made for the drugs as if the reduction had occurred. Also a new maximum limitation for each drug per month is created.

NEW/REVISED MATERIAL :
EFFECTIVE DATE : April 01, 2006
IMPLEMENTATION DATE : April 03, 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	Chapter 8, Section 60.4, Epoetin Alfa
R	Chapter 8, section 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 Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 751	Date: November 10, 2005	Change Request 4135

SUBJECT: National Monitoring Policy for EPO and Aranesp® for End Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities

I. GENERAL INFORMATION

A. Background: Medicare previously had an EPO monitoring policy that restricted review of EPO claims to post-payment review based on a 90-day rolling average of hematocrit levels. The target to trigger action was 37.5. Higher levels could be approved upon medical justification by the treating physician.

In fall 2003, the Centers for Medicare & Medicare Services (CMS) solicited information from the ESRD community in order to develop a national claims monitoring policy for erythropoietin administered to ESRD patients in renal dialysis facilities. We found there is considerable natural variability in individual patient hematocrit levels, making it difficult to consistently maintain a hematocrit within the narrow range of 33-36.

B. Policy: Effective for services furnished on or after April 1, 2006, Medicare is implementing a national claims monitoring policy for EPO and Aranesp® in the Medicare ESRD in-facility dialysis population. 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 the products warrant postponing monitoring until the hematocrit reaches higher levels. In order to allow for unanticipated increases in hematocrit, CMS will not require contractors to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin above 13.0). For claims with hematocrit readings above the threshold of 39.0 (hemoglobin above 13.0), the dose of the drug should be reduced by 25% over the preceding month. If the dose has been reduced by 25%, modifier GS should be reported on the claim and payment will be made based on the reported dosage. Modifier GS is defined as “Dosage of EPO or Darbepoetin Alfa has been reduced 25% of preceding month’s dosage.”

For claims with hematocrit levels above 39.0 (hemoglobin above 13.0) without modifier GS, Medicare will reduce the dosage payable by 25%. This payment reduction may be appealed under the normal appeal process. Beneficiaries, physicians, and/or renal facilities may submit medical documentation that they believe justifies the need for higher hematocrit levels as part of their appeal.

Medicare will not make payment for dosages of EPO in excess of 500,000 IUs per month or Aranesp® in excess of 1500 mcg per month since dosages at these levels are likely the result of typographical errors rather than accurate dosage reports.

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	
4135.1	For claim bill type 72x containing EPO (HCPCS Q4055 (J0886 effective 1/1/06)) and value code 49 amount is equal to or less than 39.0 or value code 48 amount is equal to or less than 13.0, Medicare systems shall continue to pay according to the dosage reported under value code 68.					X				
4135.1.1	When value code 49 amount is greater than 39.0 or value code 48 amount is greater than 13.0, Medicare systems shall look for the presence of modifier GS on the line item for EPO (Q4055 (J0886 effective 1/1/06)).					X				
4135.1.2	When modifier GS is present, Medicare systems shall continue to pay according to the dosage reported under value code 68.					X				
4135.1.3	When modifier GS is <u>not</u> present, Medicare systems shall calculate the payment by applying a 25% reduction to the payment for EPO.					X				
4135.1.4	Medicare contractors shall hold providers liable for the 25% reduction unless occurrence code 32 is present on the claim or modifier GA is present on the line.	X				X				
4135.1.5	Medicare systems shall create a line level edit for EPO (Q4055 (J0886 effective 1/1/06)) units exceeding 500,000 per claim (value code 68 amount exceeds 500,000).					X				
4135.1.6	Medicare contractors shall return to provider claims containing EPO units exceeding 500,000 as medically unbelievable.	X								
4135.2	For claim bill type 72x containing Aranesp® (HCPCS Q4054 (J0882 effective 1/1/06)) and value code 49 amount is equal to or less than 39.0 or value code 48 amount is equal to or less than 13.0, Medicare systems shall continue to					X				

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	pay according to the dosage reported under the units field.									
4135.2.1	When value code 49 amount is greater than 39.0 or value code 48 amount is greater than 13.0, Medicare systems shall look for the presence of modifier GS on the line item for Aranesp® (Q4054 (J0882 effective 1/1/06)).					X				
4135.2.2	When modifier GS is present, Medicare systems shall continue to pay according to the dosage reported under the units field.					X				
4135.2.3	When modifier GS is <u>not</u> present, Medicare systems shall calculate the payment by applying a 25% reduction to the payment for Aranesp®.					X				
4135.2.4	Medicare contractors shall hold providers liable for the 25% reduction unless occurrence code 32 is present on the claim or modifier GA is present on the line.	X				X				
4135.2.5	Medicare systems shall create a line level edit for Aranesp® (Q4054 (J0882 effective 1/1/06)) units exceeding 1500 per claim. (note: 1 unit = 1 mcg)					X				
4135.2.6	Medicare contractors shall return to provider claims containing Q4054 (J0882 effective 1/1/06) with units exceeding 1500 as medically unbelievable	X								

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)					
		FI	RHHI	Carr	DME	Shared System Maintainers	Other

						FISS	MCS	VMS	CWF	
4135.3	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "Medlearn 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 Medlearn 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: NA

X-Ref Requirement #	Instructions
4135.1.3 and 4135.2.3	Notify providers of reduction in payment with adjustment reason code 153 – Payment adjusted because the payer deems the information submitted does not support this dosage.
4135.1.3 and 4135.2.3	Notify beneficiaries of the reduction in payment with MSN code 15.15 – Payment has been reduced because information provided does not support the need for this item as billed.

B. Design Considerations: NA

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: NA

D. Contractor Financial Reporting /Workload Impact: NA

E. Dependencies: NA

F. Testing Considerations: NA

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: April 1, 2006 **Implementation Date:** April 3, 2006 **Pre-Implementation Contact(s):** Policy: Jackie Sheridan-Moore 410-786-4635, Jackie.sheridan@cms.hhs.gov, Claims Processing: Wendy Tucker 410-786-3004, Wendy.Tucker@cms.hhs.gov **Post-Implementation Contact(s):** ROs	**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. 751, Issued: 11-10-05, Effective: 04-01-06, Implementation: 04-03-06)

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 in the Medicare renal dialysis facility population. 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 monitoring until the hematocrit reaches higher levels. In order to allow for unanticipated increases in hematocrit, CMS will not require contractors to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). 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 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 by 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. 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 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.

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. 751, Issued: 11-10-05, Effective: 04-01-06, Implementation: 04-03-06)

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® in the Medicare renal dialysis facility population. 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 monitoring until the hematocrit reaches higher levels. In order to allow for unanticipated increases in hematocrit, CMS will not require contractors to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). For 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. 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.

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."