

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 1285</b>	<b>Date: JULY 13, 2007</b>
	<b>Change Request 5545</b>

**Subject: Renal Dialysis Facility Line Item Billing Requirement for Epoetin Alfa (EPO) Submitted on End Stage Renal Disease (ESRD) Claims**

**I. SUMMARY OF CHANGES:** This instruction completes the implementation of ESRD line item billing for Renal Dialysis Facilities by providing instructions required to submit line item billing EPO on ESRD claims with dates of service on or after January 1, 2008

**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	8/50.3/ Required Information for In-Facility Claims Paid Under the Composite Rate
R	8/60.4.1/ Epoetin Alfa (EPO) Facility Billing Requirements
R	8/60.4.3/ Payment Amount for Epoetin Alfa (EPO)
R	8/60.4.4.1/ Self Administered EPO Supply
R	8/60.7.1/ Darbepoetin Alfa (Aranesp) Facility Billing Requirements

**III. FUNDING:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2008 operating budgets.

#### **IV. ATTACHMENTS:**

**Business Requirements**

**Manual Instruction**

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

# Attachment - Business Requirements

<b>Pub. 100-04</b>	<b>Transmittal: 1285</b>	<b>Date: July 13, 2007</b>	<b>Change Request: 5545</b>
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**SUBJECT: Renal Dialysis Facility Line Item Billing Requirement for Epoetin Alfa (EPO) Submitted on End Stage Renal Disease (ESRD) Claims**

**Effective Date:** January 1, 2008

**Implementation Date:** January 7, 2008

## I. GENERAL INFORMATION

**A. Background:** Change Request 5039 “Line Item Billing Requirement for ESRD Claims” implemented the first stage of the ESRD line item billing requirement beginning on April 1, 2007. This instruction completes the implementation of ESRD line item billing by providing instructions required to submit line item billing for EPO on ESRD claims with dates of service on or after January 1, 2008. Line item billing allows for EPO to be billed in the same manner as other separately payable drugs.

**B. Policy:** For claims with dates of service on or after January 1, 2008, RDFs will bill for each administration of EPO on a separate line indicating the line item date of service for the administration. The units reported on the claim line for EPO are multiplied by the total units defined by the HCPCS to reflect the dosage per administration. This is the same method of billing applicable to all other separately payable drugs. RDFs will no longer be required to report the value code 68 with the total monthly dosage. The total number of administrations of EPO will be determined by the total number of lines on the claim billing for EPO. When RDFs report the GS modifier it is not required to be reported on every EPO line item. The GS modifier should be reported on the line item(s) that represent an administration of EPO at the reduced dosage following existing instructions in Publication 100-04 Medicare Claims Processing, Chapter 8, Section 60.4. No payment reduction is made when the GS modifier is present on the claim.

Supplies of EPO and Aranesp for self-administration should be billed according to the pre-determined plan of care schedule provided to the beneficiary. RDFs must submit a separate line item for each date an administration is expected to be performed with the expected dosage. In the event that the schedule was changed, the provider should note the changes in the medical record and bill according to the revised schedule. For patients beginning to self administer EPO or Aranesp at home receiving an extra month supply of the drug, RDFs should bill the one month reserve supply on one claim line and include modifier EM - Emergency Reserve Supply (for ESRD benefit only). RDFs should include condition code 70 on claims billing for home dialysis patients that self-administer anemia management drugs, including EPO and Aranesp.

## II. BUSINESS REQUIREMENTS TABLE

Use “Shall” to denote a mandatory requirement

Number	Requirement	Responsibility (place an “X” in each applicable column)							
		A	D	F	C	D	R	Shared-System Maintainers	OTHER
		/	M	I	A	M	H		

										F I S S	M C S	V M S	C W F	
5545.1	Medicare contractors shall require EPO (Q4081) to be line item billed as described in the Policy Section 1.B. above for 72x claims with dates of service on or after January 1, 2008.	X		X						X				
5545.2	Medicare systems shall no longer require the value code 68 for EPO units for 72x claims with dates of service on or after January 1, 2008.									X				
5545.3	Medicare systems shall calculate the EPO payment based on the units reported on the line for 72x claims with dates of service on or after January 1, 2008.									X				
5545.4	Medicare systems shall calculate the number of administrations of EPO per month by adding the number of EPO lines reported on the 72x claim for dates of service on or after January 1, 2008.									X				
5545.4.1	Medicare systems shall not count an EPO line reported with the modifier EM toward the monthly limitation of administrations (13 per 30 days/14 per 31 days) for 72x claims with dates of service on or after January 1, 2008.									X				
5545.4.2	Medicare systems shall not count an Aranesp line (J0882) reported with the modifier EM toward the monthly limitation of administrations (5 per 30/31 days) for 72x claims with dates of service on or after January 1, 2008.									X				
5545.5	Medicare systems shall allow the same line item date of service for two lines billing for EPO when one of the lines has the modifier EM present. (The lines should not be rolled up.)									X				
5545.5.1	Medicare systems shall allow the same line item date of service for two lines billing for Aranesp when one of the lines has the modifier EM present. (The lines should not be rolled up.)									X				
5545.6	Medicare systems shall return to the provider (RTP) 72x claims with dates of service on or after January 1, 2008 that contain more than one EPO line with modifier EM present.									X				
5545.6.1	Medicare systems shall return to the provider (RTP) 72x claims with dates of service on or after January 1, 2008 that contain more than one Aranesp line with modifier EM present.									X				
5545.7	Medicare systems shall calculate the monthly EPO dosage for the medically unbelievable edit by adding up the dosage reported on each line for EPO for 72x 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  M A C	D M E  M A C	F I	C A R R I E R	D M E R C	R H H I	Shared-System Maintainers				OTHER
								F I S S	M C S	V M S	C W F	
5545.8	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> 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 one 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

**A. For any recommendations and supporting information associated with listed requirements, use the box below:**

*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:
5545.9	Medicare systems shall not apply the EPO monitoring policy 25% payment reduction to any lines on the claim when a GS modifier is reported on the claim. Note: CMS does not require the GS modifier to be reported on every line billing for EPO.
5545.9.1	Medicare systems shall apply the EPO Monitoring Policy 25% payment reduction when applicable under existing policy (Pub.100-04, Chapter 8, Section 60.4.) to all lines of EPO on the claim.

**B. For all other recommendations and supporting information, use this space:**

#### V. CONTACTS

**Pre-Implementation Contact(s):** Wendy Tucker 410-786-3004, [Wendy.Tucker@cms.hhs.gov](mailto:Wendy.Tucker@cms.hhs.gov) or Jason Kerr 410-786-2123, [Jason.Kerr@cms.hhs.gov](mailto:Jason.Kerr@cms.hhs.gov)

**Post-Implementation Contact(s):** Appropriate Regional Office.

## **VI. FUNDING**

**A. For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC), use only one of the following statements:**

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), use the following statement:**

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.

## **50.3 - Required Information for In-Facility Claims Paid Under the Composite Rate**

*(Rev. 1285; Issued: 07-13-07; Effective: 01-01-08; Implementation: 01-07-08)*

*The electronic form required for billing ESRD claims is the ANSI X12N 837 Institutional claim transaction. Since the data structure of the 837 transaction is difficult to express in narrative form and to provide assistance to small providers excepted from the electronic claim requirement, the instructions below are given relative to the UB-04 (Form CMS-1450) hardcopy form. A table to crosswalk UB-04 form locators to the 837 transaction is found in Chapter 25, §100.*

### **Form Locator (FL) 4 - Type of Bill Code Structure**

Acceptable codes for Medicare are:

721 - Admit Through Discharge Claim - This code is used for a bill encompassing an entire course of outpatient treatment for which the provider expects payment from the payer.

722 - Interim - First Claim - This code is used for the first of an expected series of payment bills for the same course of treatment.

723 - Interim - Continuing Claim - This code is used when a payment bill for the same course of treatment is submitted and further bills are expected to be submitted later.

724 - Interim - Last Claim - This code is used for a payment bill which is the last of a series for this course of treatment. The “Through” date of this bill (FL 6) is the discharge date for this course of treatment.

727 - Replacement of Prior Claim - This code is used when the provider wants to correct (other than late charges) a previously submitted bill. The previously submitted bill needs to be resubmitted in its entirety, changing only the items that need correction. This is the code used for the corrected or “new” bill.

728 - Void/Cancel of a Prior Claim - This code indicates this bill is a cancel-only adjustment of an incorrect bill previously submitted. Cancel-only adjustments should be used only in cases of incorrect provider identification numbers, incorrect HICNs, duplicate payments and some OIG recoveries. For incorrect provider numbers or HICNs, a corrected bill is also submitted using a code 721.

**FL 6 - Statement Covers Period (From-Through) - Hospital-based and independent renal dialysis facilities:**

The beginning and ending service dates of the period included on this bill. Note: ESRD services are subject to the monthly billing requirements for repetitive services.

### **FLs 24, 25, 26, 27, 28, 29 and 30 - Condition Codes**

Hospital-based and independent renal facilities complete these items. Note that one of the codes 71-76 is applicable for every bill. Special Program Indicator codes A0-A9 are not required.

Condition Code Structure (only codes affecting Medicare payment/processing are shown).

02 - Condition is Employment Related - Providers enter this code if the patient alleges that the medical condition causing this episode of care is due to environment/events resulting from employment.

04 - Patient is HMO Enrollee - Providers enter this code to indicate the patient is a member of an HMO.

59 – Non-Primary ESRD Facility – Providers enter this code to indicate that ESRD beneficiary received non-scheduled or emergency dialysis services at a facility other than his/her primary ESRD dialysis facility.

71 - Full Care in Unit - Providers enter this code to indicate the billing is for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility.

72 - Self-Care in Unit - Providers enter this code to indicate the billing is for a patient who managed his own dialysis in a hospital or renal dialysis facility.

73 - Self-Care in Training - Providers enter this code to indicate the billing is for special dialysis services where a patient and his/her helper (if necessary) were learning to perform dialysis.

76 - Back-up In-facility Dialysis - Providers enter this code to indicate the billing is for a home dialysis patient who received back-up dialysis in a facility.

#### **FLs 32, 33, 34 and 35 - Occurrence Codes and Dates**

Codes(s) and associated date(s) defining specific events(s) relating to this billing period are shown. Event codes are two alpha-numeric digits, and dates are shown as six numeric digits (MM-DD-YY). When occurrence codes 01-04 and 24 are entered, make sure the entry includes the appropriate value code in FLs 39-41, if there is another payer involved.

Fields 32A-35A must be completed before fields 32B-35B are used.

Occurrence and occurrence span codes are mutually exclusive. Occurrence codes have values from 01 through 69 and A0 through L9. Occurrence span codes have values from 70 through 99 and M0 through Z9.

24 - Date Insurance Denied - Code indicates the date of receipt of a denial of coverage by a higher priority payer.

33 - First Day of Medicare Coordination Period for ESRD Beneficiaries Covered by an EGHP - Code indicates the first day of the Medicare coordination period during which Medicare benefits are payable under an EGHP. This is required only for ESRD beneficiaries.

#### **FL 36 - Occurrence Span Code and Dates**

Code(s) and associated beginning and ending dates(s) defining a specific event relating to this billing period are shown. Event codes are two alpha-numeric digits and dates are shown numerically as MM-DD-YY.

74 - Noncovered Level of Care - This code is used for repetitive Part B services to show a period of inpatient hospital care or of outpatient surgery during the billing period. Use of this code will not be necessary for ESRD claims with dates of service on or after April 1, 2007 due to the requirement of ESRD line item billing.

FL 37 – Internal Control Number (ICN) Document Control Number (DCN) Required for all provider types on adjustment requests. (Bill Type/FL=XX7). All providers requesting an adjustment to a previous processed claim insert the ICN/DCN of the claims to be adjusted. Payer A’s ICN/DCN should be shown for line A of FL 37.

**FLs 39, 40, and 41 - Value Codes and Amounts**

Code(s) and related dollar amount(s) identify monetary data that are necessary for the processing of this claim. The codes are two alphanumeric digits and each value allows up to nine numeric digits (0000000.00). Negative amounts are not allowed, except in FL 41. Whole numbers or non-dollar amounts are right justified to the left of the dollars and cents delimiter. Some values are reported as cents, so refer to specific codes for instructions. If more than one value code is shown for a billing period, show the codes in ascending alphanumeric sequence. There are four lines of data, line “A” through line “B.” FLs 39A through 41A are used before FLs 39B through 41B (i.e., the first line is used up before the second line is used and so on).

Value Code Structure (Only codes used to bill Medicare are shown.):

06 - Medicare Blood Deductible - Code indicates the amount the patient paid for un-replaced deductible blood.

13 - ESRD Beneficiary in the 30- Month Coordination Period With an EGHP - Code indicates that the amount shown is that portion of a higher priority EGHP payment on behalf of an ESRD beneficiary that applies to covered Medicare charges on this bill. If the provider enters six zeros (0000.00) in the amount field, it is claiming a conditional payment because the EGHP has denied coverage or there has been a substantial delay in its payment. Where the provider received no payment or a reduced payment because of failure to file a proper claim, this is the amount that would have been payable had it filed a proper claim.

37 - Pints of Blood Furnished - Code indicates the total number of pints of blood or units of packed red cells furnished, whether or not replaced. Blood is reported only in terms of complete pints rounded upwards, e.g., 1 1/4 pints is shown as 2 pints. This entry serves a basis for counting pints towards the blood deductible. Hospital-based and independent renal facilities must complete this item.

38 - Blood Deductible Pints - Code indicates the number of un-replaced deductible pints of blood supplied. If all deductible pints furnished have been replaced, no entry is made. Hospital-based and independent renal facilities must complete this item.

39 - Pints of Blood Replaced - Code indicates the total number of pints of blood donated on the patient’s behalf. Where one pint is donated, one pint is replaced. If arrangements have been made for replacement, pints are shown as replaced. Where the provider charges only for the blood processing and administration, i.e., it does not charge a “replacement deposit fee” for un-replaced pints, the blood is considered replaced for purposes of this item. In such cases, all blood charges are shown under the 039x revenue

code series, Blood Administration. Hospital-based and independent renal facilities must complete this item.

44 - Amount Provider Agreed To Accept From Primary Payer When This Amount is Less Than Charges But Higher than Payment Received - Code indicates the amount shown is the amount the provider was obligated or required to accept from a primary payer as payment in full when that amount is less than the charges but higher than amount actually received. A Medicare secondary payment is due.

47 - Any Liability Insurance - Code indicates amount shown is that portion from a higher priority liability insurance made on behalf of a Medicare beneficiary that the provider is applying to Medicare covered services on this bill. If six zeros (0000.00) are entered in the amount field, the provider is claiming conditional payment because there has been substantial delay in the other payer's payment.

48 - Hemoglobin Reading - Code indicates the hemoglobin reading taken before the last administration of Erythropoietin (EPO) during this billing cycle. This is usually reported in three positions with a decimal. Use the right of the delimiter for the third digit.

Effective January 1, 2006 the definition of value code 48 is changed to indicate the patient's most recent hemoglobin reading taken before the start of the billing period.

49 - Hematocrit Reading - Code indicates the hematocrit reading taken before the last administration of EPO during this billing cycle. This is usually reported in two positions (a percentage) to the left of the dollar/cents delimiter. If the reading is provided with a decimal, use the position to the right of the delimiter for the third digit.

Effective January 1, 2006 the definition of value code 49 is changed to indicate the patient's most recent hematocrit reading taken before the start of the billing period.

67 - Peritoneal Dialysis - The number of hours of peritoneal dialysis provided during the billing period. Count only the hours spent in the home. Exclude travel time. Report amount in whole units right-justified to the left of the dollar/cents delimiter. (Round to the nearest whole hour.)

Reporting value code 67 will not be required for claims with dates of service on or after April 1, 2007.

68 - Erythropoietin Units - Code indicates the number of units of administered EPO relating to the billing period and reported in whole units to the left of the dollar/cents delimiter. NOTE: The total amount of EPO injected during the billing period is reported. If there were 12 doses injected, the sum of the units administered for the 12 doses is reported as the value to the left of the dollar/cents delimiter.

*Medicare no longer requires value code 68 for claims with dates of service on or after January 1, 2008.*

71 - Funding of ESRD Networks - Code indicates the amount of Medicare payment reduction to help fund the ESRD networks. This amount is calculated by the FI and forwarded to CWF. (See [§120](#) for discussion of ESRD networks).

A8 – Weight of Patient – Code indicates the weight of the patient in kilograms. The weight of the patient should be measured after the last dialysis session of the month.

A9 – Height of Patient – Code indicates the height of the patient in centimeters. The height of the patient should be measured during the last dialysis session of the month. This height is as the patient presents.

**FL 42 - Revenue Codes**

The revenue code for the appropriate treatment modality under the composite rate is billed (e.g., 0821 for hemodialysis). Services included in the composite rate and related charges must not be shown on the bill separately. Hospitals must maintain a log of these charges in their records for cost apportionment purposes.

Services which are provided but which are not included in the composite rate may be billed as described in sections that address those specific services.

082X - Hemodialysis - Outpatient or Home Dialysis - A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed directly from the blood. Detailed revenue coding is required. Therefore, services may not be summed at the zero level.

0 - General Classification	HEMO/OP OR HOME
1 – Hemodialysis/Composite or other rate	HEMO/COMPOSITE
2 - Home Supplies	HEMO/HOME/SUPPL
3 - Home Equipment	HEMO/HOME/EQUIP
4 - Maintenance 100%	HEMO/HOME/100%
5 - Support Services	HEMO/HOME/SUPSERV
9 - Other Hemodialysis Outpatient	HEMO/HOME/OTHER

083X - Peritoneal Dialysis - Outpatient or Home - A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed indirectly by instilling a special solution into the abdomen using the peritoneal membrane as a filter.

0 - General Classification	PERITONEAL/OP OR HOME
1 - Peritoneal/Composite or other rate	PERTNL/COMPOSITE
2 - Home Supplies	PERTNL/HOME/SUPPL
3 - Home Equipment	PERTNL/HOME/EQUIP
4 - Maintenance 100%	PERTNL/HOME/100%
5 - Support Services	PERTNL/HOME/SUPSERV



#### **FL 44 - HCPCS/Rates**

All hemodialysis claims must include HCPCS 90999 on the line reporting revenue code 082x.

Modifiers are required for ESRD Billing for Adequacy of Hemodialysis. For information on reporting the urea reduction ratio with modifiers G1 through G6, see section 50.9 of this chapter.

For information on reporting the GS modifier for reporting a dosage reduction of epoetin alfa or darbepoetin alfa, see sections 60.4 and 60.7 of this chapter.

#### **FL 45 – Service Date**

Report the line item date of service for each dialysis session and each separately payable item or service.

#### **FL 46 - Units of Service**

Hospital-based and independent renal facilities must complete this item. The entries quantify services by revenue category, e.g., number of dialysis treatments. Units are defined as follows:

0634 - Erythropoietin (EPO) - Administrations, i.e., the number of times an injection of less than 10,000 units of EPO was administered. *For claims with dates of service on or after January 1, 2008, facilities use the units field as a multiplier of the dosage description in the HCPCS to arrive at the dosage amount per administration.*

0635 - Erythropoietin (EPO) - Administrations, i.e., the number of times an injection of 10,000 units or more of EPO was administered. *For claims with dates of service on or after January 1, 2008, facilities use the units field as a multiplier of the dosage description in the HCPCS to arrive at the dosage amount per administration.*

082X - (Hemodialysis) - Sessions

083X - (Peritoneal) - Sessions

084X - (CAPD) - Days covered by the bill

085X - (CCPD) - Days covered by the bill

Effective April 1, 2007, the implementation of ESRD line item billing requires that each dialysis session be billed on a separate line. As a result, claims with dates of service on or after April 1, 2007 should not report units greater than 1 for each dialysis revenue code line billed on the claim.

#### **FL 47 - Total Charges**

Hospital-based and independent renal facilities must complete this item. Hospital-based facilities show their customary charges that correspond to the appropriate revenue code in FL 42. They must not enter their composite or the EPO` rate as their charge. Independent facilities may enter their composite and/or EPO rates.

Neither revenue codes nor charges for services included in the composite rate may be billed separately (see [§90.3](#) for a description). Hospitals must maintain a log of these charges in their records for cost apportionment purposes.

Services which are provided but which are not included in the composite rate may be billed as described in sections that address those specific services.

The last revenue code entered in FL 42 as 0001 represents the total of all charges billed.

**FL 67 – Principal Diagnosis Code**

Hospital-based and independent renal facilities must complete this item and it should include a diagnosis of end stage renal disease.

**60.4.1 - Epoetin Alfa (EPO) Facility Billing Requirements**

*(Rev. 1285; Issued: 07-13-07; Effective: 01-01-08; Implementation: 01-07-08)*

Revenue codes required for reporting EPO:

Revenue Codes	Dates of Service			
	Bill Type 72x	Bill Type 12x	Bill type 13x	Bill type 85x
0634 – administrations under 10,000 units	1/1/04 – present	4/1/06 – present	1/1/04 – present	1/1/04 – present
0635 – administrations of 10,000 units or more	1/1/04 – present	4/1/06 – present	1/1/04 – present	1/1/04 – present
0636 – detailed drug coding	N/A	1/1/04 – 3/31/06	N/A	N/A

For additional hospital billing instructions related to bill types 12x, 13x and 85x see also sections 60.4.3.1 and 60.4.3.2 of this chapter.

The HCPCS code for EPO must be included:

HCPCS	HCPCS Description	Dates of Service
Q4055	Injection, Epoetin alfa, 1,000 units (for ESRD on Dialysis)	1/1/2004 through 12/31/2005
J0886	Injection, Epoetin alfa, 1,000 units (for ESRD on Dialysis)	1/1/2006 through 12/31/2006
Q4081	Injection, Epoetin alfa, 100	1/1/2007 to present

	units (for ESRD on Dialysis)	
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The number of units of EPO administered during the billing period is reported with value code 68. *Medicare no longer requires value code 68 for claims with dates of service on or after January 1, 2008. Each administration of epoetin alfa (EPO) is reported on a separate line item with the units reported used as a multiplier by the dosage description in the HCPCS to arrive at the dosage per administration.*

*Append the GS modifier to report a line item that represents an administration of EPO at the reduced dosage following existing instructions in section 60.4 of this chapter.*

The hematocrit reading taken prior to the last administration of EPO during the billing period must also be reported on the UB-92/Form CMS-1450 with value code 49. Effective January 1, 2006 the definition of value code 49 used to report the hematocrit reading is changed to indicate the patient's most recent hematocrit reading taken **before** the start of the billing period.

The hemoglobin reading taken during the billing period must be reported on the UB-92/Form CMS-1450 with value code 48. Effective January 1, 2006 the definition of value code 48 used for the hemoglobin reading is changed to indicate the patient's most recent hemoglobin reading taken **before** the start of the billing period.

To report a hemoglobin or hematocrit reading for a new patient on or after January 1, 2006, the provider should report the reading that prompted the treatment of epoetin alfa. The provider may use results documented on form CMS 2728 or the patient's medical records from a transferring facility.

The maximum number of administrations of EPO for a billing cycle is 13 times in 30 days and 14 times in 31 days.

### **60.4.3 - Payment Amount for Epoetin Alfa (EPO)**

*(Rev. 1285; Issued: 07-13-07; Effective: 01-01-08; Implementation: 01-07-08)*

Dates of service prior to January 1, 2005, the FI pays the facility \$10 per 1,000 units of EPO administered, rounded to the nearest 100 units (i.e., \$1.00 per 100 units). Effective January 1, 2005, EPO will be paid based on the ASP Pricing File. Also 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. Where EPO is furnished by a supplier that is not a facility, the DMERC pays at the same rate.

Physician payment is calculated through the drug payment methodology described in Chapter 17 of the Claims Processing Manual.

**EXAMPLE:** The billing period is 2/1/94 - 2/28/94.

The facility provides the following:

<b>Date</b>	<b>Units</b>	<b>Date</b>	<b>Units</b>
2/1	3000	2/15	2500
2/4	3000	2/18	2500
2/6	3000	2/20	2560
2/8	3000	2/22	2500
2/11	2500	2/25	2000
2/13	2500	2/27	2000

Total 31,060 units

For value code 68, the facility enters 31,060. The 31,100 are used to determine the rate payable. This is 31,060 rounded to the nearest 100 units. The amount payable is  $31.1 \times \$10 = \$311.00$ . In their systems, FIs have the option of setting up payment of \$1.00 per 100 units. Effective January 1, 2005, EPO will be paid based on the ASP Pricing File.

*Effective January 1, 2008, payment is calculated on a renal dialysis facility claim at the line level by multiplying the rate from the ASP pricing file by the number of units reported on the line billing for EPO.*

**EXAMPLE:**  $311 \times \$1.00 = \$311.00$

If an ESRD beneficiary requires 10,000 units or more of EPO per administration, special documentation must be made in the medical records. It must consist of a narrative report that addresses the following:

- Iron deficiency. Most patients need supplemental iron therapy while being treated, even if they do not start out iron deficient;
- Concomitant conditions such as infection, inflammation, or malignancy. These conditions must be addressed to assure that EPO has maximum effect;
- Unrecognized blood loss. Patients with kidney disease and anemia may easily have chronic blood loss (usually gastrointestinal) as a major cause of anemia. In those circumstances, EPO is limited in effectiveness;
- Concomitant hemolysis, bone marrow dysplasia, or refractory anemia for a reason other than renal disease, e.g., aluminum toxicity;
- Folic acid or vitamin B12 deficiencies;
- Circumstances in which the bone marrow is replaced with other tissue, e.g., malignancy or osteitis fibrosa cystica; and

Patient's weight, the current dose required, a historical record of the amount that has been given, and the hematocrit response to date.

### 60.4.4.1 - Self Administered EPO Supply

*(Rev. 1285; Issued: 07-13-07; Effective: 01-01-08; Implementation: 01-07-08)*

Initially, facilities may bill for up to a 2-month supply of EPO for Method I beneficiaries who meet the criteria for selection for self-administration. After the initial two months' supply, the facility will bill for one month's supply at a time. Condition code 70 is used to indicate payment requested for a supply of EPO furnished a beneficiary. Usually, revenue code 0635 would apply since the supply would be over 10,000 units. Facilities leave FL 46, Units of Service, blank since they are not administering the drug. For value code 68, they enter the total amount of the supply.

*For claims with dates of service on or after January 1, 2008, supplies of EPO for self administration should be billed according to the pre-determined plan of care schedule provided to the beneficiary. Submit a separate line item for each date an administration is expected to be performed with the expected dosage. In the event that the schedule was changed, the provider should note the changes in the medical record and bill according to the revised schedule. For patients beginning to self administer EPO at home receiving an extra month supply of the drug, bill the one month reserve supply on one claim line and include modifier EM defined as "Emergency Reserve Supply (for ESRD benefit only)".*

*Condition code 70 should be reported on claims billing for home dialysis patients that self administer anemia management drugs including epoetin alfa and darbepoetin alfa.*

### 60.7.1 – Darbepoetin Alfa (Aranesp) Facility Billing Requirements

*(Rev. 1285; Issued: 07-13-07; Effective: 01-01-08; Implementation: 01-07-08)*

Revenue code 0636 is used to report Aranesp.

The HCPCS code for aranesp must be included:

HCPCS	HCPCS Description	Dates of Service
Q4054	Injection, darbepoetin alfa, 1mcg (for ESRD on Dialysis)	1/1/2004 through 12/31/2005
J0882	Injection, darbepoetin alfa, 1mcg (for ESRD on Dialysis)	1/1/2006 to present

The hematocrit reading taken prior to the last administration of Aranesp during the billing period must also be reported on the UB-92/Form CMS-1450 with value code 49. *For claims with dates of service on or after April 1, 2006, a hemoglobin reading may be reported on Aranesp claims using value code 48.*

Effective January 1, 2006 the definition of value code *48 and* 49 used to report the hemoglobin and hematocrit readings are changed to indicate the patient's most recent reading taken **before** the start of the billing period.

To report a hematocrit *or hemoglobin* reading for a new patient on or after January 1, 2006, the provider should report the reading that prompted the treatment of darbepoetin alfa. The provider may use results documented on form CMS 2728 or the patient's medical records from a transferring facility.

The payment allowance for Aranesp is the only allowance for the drug and its administration when used for ESRD patients. 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. The maximum number of administrations of Aranesp for a billing cycle is 5 times in 30/ 31days.