
CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 118

Date: MARCH 5, 2004

CHANGE REQUESTS 2984

**THE ATTACHED CR REPLACES THE CONFIDENTIAL REQUIREMENT,
FILE NAME R19_OTN COMMUNICATED ON NOVEMBER 7, 2003.**

I. SUMMARY OF CHANGES: We are making changes to reflect billing policy for Darbepoetin Alfa (Aranesp) and Epoetin Alfa (EPO).

NEW/REVISED MATERIAL - EFFECTIVE DATE: April 1, 2004

***IMPLEMENTATION DATE: April 5, 2004**

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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:

(R = REVISED, N = NEW, D = DELETED –

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	8/Table of Contents
R	8/60/60.4 Epoetin Alfa (EPO)
R	8/60/60.4.1/Epoetin Alfa (EPO) Facility Billing Requirements Using UB-92/Form CMS-1450
R	8/60/60.4.2/Epoetin Alfa (EPO) Supplier Billing Requirements (Method II) on the Form CMS-1500
R	8/60/60.4.2.1/Other Information Required on the Form CMS-1500 for Epoetin Alfa (EPO)
R	8/60/60.4.2.2/Completion of Subsequent Form CMS-1500 Claims for Epoetin Alfa (EPO)
R	8/60/60.4.3/ Payment Amount for Epoetin Alfa (EPO)
R	8/60/60.4.3.1/ Payment for Epoetin Alfa (EPO) in Other Settings
R	8/60/60.4.3.2/ Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments
R	8/60/60/60.4.4/ Epoetin Alfa (EPO) Furnished to Home Patients
N	8/60/60.7/ Darbepoetin Alfa (Aranesp) for ESRD Patients
N	8/60/60.7.1/ Darbepoetin Alfa (Aranesp) Facility Billing Requirements Using UB-92/Form CMS-1450
N	8/60/60.7.2/ Darbepoetin Alfa (Aranesp) Supplier Billing Requirements (Method II) on the Form CMS-1500 and Electronic Equivalent
N	8/60/60.7.2.1/ Other Information Required on the Form CMS-1500 for

	Darbepoetin Alfa (Aranesp)
N	8/60/60.7.2.2/ Completion of Subsequent Form CMS-1500 Claims for Darbepoetin Alfa (Aranesp)
N	8/60/60.7.3/ Payment Amount for Darbepoetin Alfa (Aranesp)
N	8/60/60.7.3.1/ Payment for Darbepoetin Alfa (Aranesp) in Other Settings
N	8/60/60.7.3.2/ Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department
N	8/60/60.7.4/ Darbepoetin Alfa (Aranesp) Furnished to Home Patients
R	8/60/90.5.1/ Billable UB-92 Revenue Codes Under Method II

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment – Business Requirements

Pub. 100-04	Transmittal: 118	Date: March 5, 2004	Change Request: 2984
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THE ATTACHED CR REPLACES THE CONFIDENTIAL REQUIREMENT, FILE NAME R19_OTN COMMUNICATED ON NOVEMBER 7, 2003. PLEASE DISCARD CR 2984 DATED NOVEMBER 7, 2003.

SUBJECT: Frequency Limitations for Darbepoetin Alfa (trade name Aranesp) For Treatment Of Anemia In End Stage Renal Disease (ESRD) Patients On Dialysis.

I. GENERAL INFORMATION

This notification contains instructions for frequency limitations for Darbepoetin alfa (Aranesp) for End Stage Renal Disease patients on dialysis received on or after April 1, 2004. The frequency limitations for Epoetin Alfa (trade name EPO) will remain the same. Aranesp should continue to be paid in accordance with the payment guidelines in CR2963, (One Time Notification – Change in Coding on Medicare Claims for Darbepoetin Alfa (trade name Aranesp) and Epoetin Alfa (trade name Epogen, EPO) for Treatment of Anemia in End Stage Renal Disease (ESRD) Patients on Dialysis— Transmittal 39, Dated January 6, 2004) and EPO will continue to be paid at \$10 per 1000 units.

Darbepoetin Alfa is given once a week according to its Food and Drug Administration-approved labeling. For this reason, we will allow it to be billed a maximum of 5 times during any calendar month. Coverage rules for darbepoetin alfa are the same as epoetin alfa for ESRD-related anemia.

This notification does not apply to payment of Aranesp and EPO for physicians. Physicians will continue to receive the payment established in the MMA Drug Payment Limits Pricing File.

A. Background:

Darbepoetin Alfa (Aranesp)

Section 1881(b)(11)(B) of the Social Security Act provides for payment of erythropoetin when provided to a patient determined to have ESRD. Darbepoetin alfa, a new erythropoetin like product, differs from epoetin alfa by the addition of two carbohydrate chains, which lengthen the biologic half-life. This change affects how often the biological can be administered, and results in a decreased dosing schedule for darbepoetin alfa by comparison to epoetin alfa.

Amgen has received Food and Drug Administration approval to market darbepoetin alfa as Aranesp for treatment of anemia related to chronic renal failure, including patients both on and not on dialysis. Because darbepoetin alfa has two additional carbohydrate

side-chains, it is not structurally identical to epoetin alfa. Both products use the same biological mechanism to produce the same clinical result, stimulation of the bone marrow to produce red blood cells. However, these biologicals are dosed in different units. Epoetin alfa is dosed in units per kilograms (U/kg) of patient weight and darbepoetin alfa as Aranesp in micrograms per kilogram (mcg/kg). The difference in dosing metric is due to changes in accepted convention at the time of each product's development.

B. Policy:

CMS staff solicited relevant information from the industry, engaged in discussions with experts and industry representatives, and reviewed the available research literature as of the end of August 2003. For patients on dialysis, the data from the literature and the information submitted confirmed that darbepoetin alfa is as effective as epoetin alfa in maintaining hematocrit levels in patients with chronic kidney disease.

C. Provider Education:

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. Intermediaries and carriers (including DMERCs) shall post this article, or a direct link to this article, on their website and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the intermediaries and carriers' (including DMERCs) education article must be included in their next regularly scheduled bulletin.

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement
 “Should” denotes an optional requirement

Requirement #	Requirements	Responsibility
2984.1	The contractor shall accept darbepoetin alfa, Q4054, with the following limitations: 5 times in 30/31 days.	FI, & SSM
2984.2	The contractor shall continue using the Epoetin Alfa, Q4055, limitations of 13/14 in 30/31 days.	FI, & SSM
2984.3	The shared system must create an edit to reject any unit of measure qualifier other than UN for Aranesp, Q4054, and EPO, Q4055.	Carrier, DMERC & VIPS

III. SUPPORTING INFORMATION & POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
N/A	

B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements
N/A	

- C. **Interfaces:** N/A
- D. **Contractor Financial Reporting /Workload Impact:** N/A
- E. **Dependencies:** N/A
- F. **Testing Considerations:** N/A

SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: April 1, 2004</p> <p>Implementation Date: April 5, 2004</p> <p>Pre-Implementation Contact(s): Henry Richter, 410-786-4562 & Lynn Merritt-Nixon, 410-786-4652 (Policy)</p> <p>Pat Barrett, 410-786-0508 & Doris Barham, 410-786-6146 (FI)</p> <p>Melvia Page-Lasowski, 410-786-4727 (Carrier) Renee Hildt, 410-786-1446 (DMERC)</p> <p>Post-Implementation Contact(s): Regional Office</p>	<p>These instructions should be implemented within your current operating budget.</p>
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Medicare Claims Processing Manual

Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims

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60.4 - Epoetin Alfa (EPO)

(Rev 118, 03-05-04)

A3-3644.D.1 - D.3, PRM-1-2710.3.A - D, RDF-207.5.A - C, B3-2049.5.B, B3-2049.3.B.1, PM AB 97-2, PM AB-00-76, PM A-01-106, RDF-319

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.*

Intermediaries pay for EPO to 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.

If the beneficiary obtains EPO from a supplier for self-administration, the supplier bills the 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	<i>Separately Billable</i>	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 a renal facility, the service is not an “incident to” service and not under the “incident to” provision.

The Dialysis Outcomes Quality Initiative recommends a threshold hematocrit value range of 33 to 36 percent. National policy requires FIs and carriers to identify practitioners with an atypical number of patients with hematocrit levels above a 90-day rolling average of 37.5 percent for routine medical; review activities, such as provider education or pre-payment reviews. That is, medical documentation is not required for a single value over 36 percent. However, FIs and carriers must make a determination upon post payment review if the treating physician argues it is medically necessary to have a target hematocrit that is greater than 36 percent (which would then exceed the rolling average of 37.5 percent). These hematocrit requirements apply only to EPO furnished as an ESRD

benefit under [§1881\(b\)](#) of the Social Security Act (the 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."

60.4.1 - Epoetin Alfa (EPO) Facility Billing Requirements Using UB-92/Form CMS-1450

(Rev 118, 03-05-04)

Revenue codes 0634 and 0635 are used to report EPO. Code 0634 reports the number of administrations under 10,000 units and 0635 reports the number of administrations of 10,000 or more.

The number of units of EPO administered during the billing period is reported with value code 68.

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.

The hemoglobin reading taken during the billing period must be reported on the UB-92/Form CMS-1450 with value code 48.

The HCPCS code for EPO must be included: Q4055 – Injection, Epoetin alfa, 1,000 units (for ESRD on Dialysis).

Either the hematocrit or the hemoglobin reading is required *on the bill*. The FI must retain the hematocrit (HCT) or hemoglobin (hgb) reading in *a* format accessible to the claims process for use to average readings for a 90-day period on future claims.

The statutory payment allowance for EPO (\$10 per 1000 units) is the only allowance for the drug and its administration when used for ESRD patients. Payment for medical supplies needed for the administration of EPO, whether in the home or in a facility, is included in the Medicare payment rate for EPO.

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

60.4.2 - Epoetin Alfa (EPO) Supplier Billing Requirements (Method II) on the Form CMS-1500 and Electronic Equivalent

(Rev 118, 03-05-04)

A. Claims with dates of service prior to January 1, 2004:

For claims with dates of service prior to January 1, 2004, the correct EPO code to use is the one that indicates the patient's most recent hematocrit (HCT) (rounded to the nearest whole percent) or hemoglobin (Hgb) (rounded to the nearest g/dl) prior to the date of service of the EPO. For example, if the patient's most recent hematocrit was 20.5 percent, bill Q9921; if it was 28.4 percent, bill Q9928.

To convert actual hemoglobin to corresponding hematocrit for Q code reporting, multiply the Hgb value by 3 and round to the nearest whole number. For example, if Hgb = 8.4, report as Q9925 ($8.4 \times 3 = 25.2$, rounded down to 25).

One unit of service of EPO is reported for each 1000 units dispensed. For example if 20,000 units are dispensed, bill 20 units. If the dose dispensed is not an even multiple of 1,000, rounded down for 1 - 499 units (e.g. 20,400 units dispensed = 20 units billed), round up for 500 - 999 units (e.g. 20,500 units dispensed = 21 units billed).

Q9920 Injection of EPO, per 1,000 units, at patient HCT of 20 or less

Q9921 Injection of EPO, per 1,000 units, at patient HCT of 21

Q9922 Injection of EPO, per 1,000 units, at patient HCT of 22

Q9923 Injection of EPO, per 1,000 units, at patient HCT of 23

Q9924 Injection of EPO, per 1,000 units, at patient HCT of 24

Q9925 Injection of EPO, per 1,000 units, at patient HCT of 25

Q9926 Injection of EPO, per 1,000 units, at patient HCT of 26

Q9927 Injection of EPO, per 1,000 units, at patient HCT of 27

Q9928 Injection of EPO, per 1,000 units, at patient HCT of 28

Q9929 Injection of EPO, per 1,000 units, at patient HCT of 29

Q9930 Injection of EPO, per 1,000 units, at patient HCT of 30

Q9931 Injection of EPO, per 1,000 units, at patient HCT of 31

Q9932 Injection of EPO, per 1,000 units, at patient HCT of 32

Q9933 Injection of EPO, per 1,000 units, at patient HCT of 33

Q9934 Injection of EPO, per 1,000 units, at patient HCT of 34

Q9935 Injection of EPO, per 1,000 units, at patient HCT of 35

Q9936 Injection of EPO, per 1,000 units, at patient HCT of 36

Q9937 Injection of EPO, per 1,000 units, at patient HCT of 37

Q9938 Injection of EPO, per 1,000 units, at patient HCT of 38

Q9939 Injection of EPO, per 1,000 units, at patient HCT of 39

Q9940 Injection of EPO, per 1,000 units, at patient HCT of 40 or above.

B. Claims with Dates of Service January 1, 2004 and after

The above codes were replaced effective January 1, 2004 by Q4055. This Q code is for the injection of EPO furnished to ESRD Beneficiaries on Dialysis. The new code does not include the hematocrit. See §60.7.

Q4055 – Injection, Epoetin alfa, 1,000 units (for ESRD on Dialysis).

The DMERC shall return to provider (RTP) assigned claims for EPO, Q4055, that do not contain a HCT value. For unassigned claims, the DMERC shall deny claims for EPO, Q4055 that do not contain a HCT value.

DMERCs must use the following messages when payment for the injection (Q4055) does not meet the coverage criteria and is denied:

MSN Message 6.5—English: Medicare cannot pay for this injection because one or more requirements for coverage were not met

MSN Message 6.5—Spanish: Medicare no puede pagar por esta inyeccion porque uno o mas requisitos para la cubierta no fueron cumplidos. (MSN Message 6.5 in Spanish).

Adjustment Reason Code B:5 Payment adjusted because coverage/program guidelines were not met or were exceeded.

The DMERCs shall use the following messages when returning as unprocessable assigned claims without a HCT value:

ANSI Reason Code 16 – Claim/service lacks information, which is needed for adjudication.

Additional information is supplied using remittance advice remarks codes whenever appropriate.

Remark Code M58 – Missing/incomplete/invalid claim information. Resubmit claim after corrections.

Deductibles and coinsurance apply.

60.4.2.1 - Other Information Required on the Form CMS-1500 for Epoetin Alfa (EPO)

(Rev 118, 03-05-04)

The following information is required for EPO. Incomplete assigned claims are returned to providers for completion. Incomplete unassigned claims are *rejected. The rejection will be due to a lack of a HCT value.* Note that when a claim is submitted on paper Form CMS-1500, these items are submitted on a separate document. It is not necessary to enter them into the claims processing system. This information is used in utilization review.

- A. Diagnoses - The diagnoses must be submitted according to ICD-9-CM and correlated to the procedure. This information is in Item 21, of the Form CMS-1500.
- B. Hematocrit (HCT)/Hemoglobin (Hgb) - There are special HCPCS codes for reporting the injection of EPO *for claims with dates of service prior to January 1, 2004.* These allow the simultaneous reporting of the patient's latest HCT or Hgb reading before administration of EPO.

The physician and/or staff *are* instructed to enter a separate line item for injections of EPO at different HCT/Hgb levels. The Q code for each line items is entered in Item 24D.

1. Code Q9920 - Injection of EPO, per 1,000 units, at patient HCT of 20 or less/Hgb of 6.8 or less.
2. Codes Q9921 through Q9939 - Injection of EPO, per 1,000 units, at patient HCT of 21 to 39/Hgb of 6.9 to 13.1. For HCT levels of 21 or more, up to a HCT of 39/Hgb of 6.9 to 13.1, a Q code that includes the actual HCT levels is used. To convert actual Hgb to corresponding HCT values for Q code reporting, multiply the Hgb value by 3 and round to the nearest whole number. Use the whole number to determine the appropriate Q code.

EXAMPLES: If the patient's HCT is 25/Hgb is 8.2-8.4, Q9925 must be entered on the claim. If the patient's HCT is 39/Hgb is 12.9-13.1, Q9939 is entered.

3. Code Q9940 - Injection of EPO, per 1,000 units at patient HCT of 40 or above.

A single line item may include multiple doses of EPO administered while the patient's HCT level remained the same.

Codes Q9920-Q9940 will no longer be recognized by the system if submitted after March 31, 2004. If claims for dates of service prior to January 1, 2004 are submitted after March 31, 2004, then code Q4055 must be used.

- C. Units Administered - The standard unit of EPO is 1,000. The number of 1,000 units administered per line item is included on the claim. The physician's office enters 1 in the units field for each multiple of 1,000 units. For example, if 12,000 units are administered, 12 is entered. This information is shown in Item 24G (Days/Units) on Form CMS-1500.

In some cases, the dosage for a single line item does not total an even multiple of 1,000. If this occurs, the physician's office rounds down supplemental dosages of 0 to 499 units to the prior 1,000 units. Supplemental dosages of 500 to 999 are rounded up to the next 1,000 units.

EXAMPLES

A patient's HCT reading on August 6 was 22/Hgb was 7.3. The patient received 5,000 units of EPO on August 7, August 9, and August 11, for a total of 15,000 units. The first line of Item 24 of Form CMS-1500 shows:

Dates of Service	Procedure Code	Days or Units
8/7 - 8/11	Q9922	15

On September 13, the patient's HCT reading increased to 27/Hgb increased to 9. The patient received 5,100 units of EPO on September 13, September 15, and September 17, for a total of 15,300 units. Since less than 15,500 units were given, the figure is rounded down to 15,000. This line on the claim form shows:

Dates of Service	Procedure Code	Days or Units
9/13 - 9/17	Q9927	15

On October 16, the HCT level increased to 33/Hgb increased to 11. The patient received doses of 4,850 units on October 16, October 18, and October 20 for a total of 14,550 units. Since more than 14,500 units were administered, the figure is rounded up to 15,000. Form CMS-1500 shows:

Dates of Service	Procedure Code	Days or Units
10/16 - 10/20	Q9933	15

NOTE: Creatinine and weight identified below are required on EPO claims as applicable.

- D. Date of the Patient's most recent HCT or Hgb.
- E. Most recent HCT or Hgb level - (prior to initiation of EPO therapy).
- F. Date of most recent HCT or Hgb level - (prior to initiation of EPO therapy).
- G. Patient's most recent serum creatinine - (within the last month, prior to initiation of EPO therapy).
- H. Date of most recent serum creatinine - (prior to initiation of EPO therapy).
- I. Patient's weight in kilograms
- J. Patient's starting dose per kilogram - (The usual starting dose is 50-100 units per kilogram.)

60.4.2.2 - Completion of Subsequent Form CMS-1500 Claims for Epoetin Alfa (EPO)

(Rev 118, 03-05-04)

Subsequent claims are completed as initial claims in [§60.4.2](#), except the following fields:

- A. Diagnoses.
- B. Hematocrit or Hemoglobin – *For dates of service prior to January 1, 2004*, this is indicated by the appropriate Q code. *For dates of service January 1, 2004, and after, suppliers must indicate the beneficiary's hematocrit on the claim. (See 60.4.2.)* Claims include an EJ modifier to the Q code. This allows the contractor to identify subsequent **claims, which do not require as much information as initial claims and prevent unnecessary development.**
- C. Number of Units Administered - Subsequent claims may be submitted electronically.

60.4.3 - Payment Amount for Epoetin Alfa (EPO)

(Rev 118, 03-05-04)

A3-3644

For Method I patients, 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). Where EPO is furnished by a supplier that is not a facility, the *DMERC* pays at the same rate.

Prior to January 1, 1994, the Method I payment was \$11 per 1,000 units. The statutory payment allowance for EPO is the only allowance for the drug and its administration. Payment for medical supplies for the administration of EPO, whether in the home or in a facility, is included in the Medicare payment rate for EPO.

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

The composite rate add-on amount (the current \$10 per 1,000 unit rate and the past \$11 per 1,000 unit rate) is updated nationally by CMS. This add-on does not vary geographically and is the same for hospital-based and independent dialysis facilities.

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

The facility provides the following:

Date	Units	Date	Units
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.

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

If an ESRD beneficiary requires 10,000 units or more of EPO per administration, special documentation must accompany the claim. 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.

60.4.3.1 – Payment for Epoetin Alfa (EPO) in Other Settings

(Rev 118, 03-05-04)

A3-3644

In the hospital inpatient setting, payment is included in the DRG.

In a skilled nursing facility (SNF), payment *for EPO covered under the Part B EPO benefit* is *not* included in the prospective payment rate *for the resident's Medicare-covered SNF stay*.

In a hospice, payment is included in the hospice per diem rate.

For a service furnished by a physician or incident to a physician's service, payment is made to the physician by the carrier in accordance with the rules for "incident to" services. When EPO is administered in the renal facility, the service is not an "incident to" service and not under the "incident to" provision.

60.4.3.2 – Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments

(Rev 118, 03-05-04)

PM-A-01-106

For patients with chronic renal failure who are not yet on a regular course of dialysis, EPO administered in a hospital outpatient department is paid under the Outpatient Prospective Payment System (OPPS).

Hospitals use type of bill 13X and report charges under revenue code 0636 with HCPCS code Q0136 and without value codes 48, 49, 68 or condition codes 70 through 76.

60.4.4 – Epoetin Alfa (EPO) Furnished to Home Patients

(Rev 118, 03-05-04)

B3-4270.1

Medicare covers EPO for dialysis patients who use EPO in the home, when requirements for a patient care plan and patient selection as described in the Medicare Benefit Policy Manual, Chapter 11, are met.

When EPO is prescribed for a home patient, it may be either administered in a facility, e.g., the one shown on the Form CMS-382 (*ESRD Beneficiary Method Selection Form*) or furnished by a facility or Method II supplier for self-administration to a home patient determined to be competent to administer this drug. For EPO furnished for self-administration to Method I and Method II home patients determined to be competent, the *renal* facility bills its FI and the Method II supplier bills its DMERC. No additional payment is made for training a prospective self-administering patient or retraining an existing home patient to self-administer EPO.

Method II patients who self-administer may obtain EPO only from either their Method II supplier, or a Medicare certified ESRD facility.

In this case, the DMERC makes payment at the same rate that applies to facilities. Program payment may not be made for EPO furnished by a physician to a patient for self-administration.

60.7 – Darbepoetin Alfa (Aranesp) for ESRD Patients.

(Rev 118, 03-05-04)

Coverage rules 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.

Intermediaries pay for Aranesp to 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.

If the beneficiary obtains Aranesp from a supplier for self-administration, the supplier bills the 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

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

- **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.**

The Dialysis Outcomes Quality Initiative recommends a threshold hematocrit value range of 33 to 36 percent. National policy requires FIs and carriers to identify practitioners with an atypical number of patients with hematocrit levels above a 90-day rolling average of 37.5 percent for routine medical; review activities, such as provider education or pre-payment reviews. That is, medical documentation is not required for a single value over 36 percent. However, FIs and carriers must make a determination upon post payment review if the treating physician argues it is medically necessary to have a target hematocrit that is greater than 36 percent (which would then exceed the rolling average of 37.5 percent). These hematocrit requirements apply only to Aranesp furnished as an ESRD benefit under §1881(b) of the Social Security Act (the 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.”

60.7.1 – Darbepoetin Alfa (Aranesp) Facility Billing Requirements Using UB-92/Form CMS-1450

(Rev 118, 03-05-04)

HCPCS code Q4054 is placed in FL 44. Revenue code 0636 is used to report for ESRD patients on maintenance dialysis.

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.

The hematocrit reading is required. The FI must retain the hematocrit (HCT) reading in a format accessible to the claims process for use to average readings for a 90-day period on future claims.

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

60.7.2 Darbepoetin Alfa (Aranesp) Supplier Billing Requirements (Method II) on the Form CMS-1500 and Electronic Equivalent

(Rev 118, 03-05-04)

ESRD patients on dialysis can use Aranesp for the treatment of anemia effective January 1, 2004, the Q code for the injection of Aranesp for ESRD beneficiaries on dialysis, is Q4054.

Q4054 – Injection, Darbepoetin alfa, 1 mcg (for ESRD on Dialysis).

Method II suppliers must use Item 19 on the CMS 1500 to place the most current HCT value (Q4054). Identify HCT as “HCT = the true value HCT”. For 837P claims, the Method II supplier must supply the most current HCT value, when billing for darbepoetin alfa Q4054, in the 2400 MEA03 with a qualifier of R2 in 2400 MEA02.

DMERCs must apply coverage rules to Aranesp in the same manner that they apply them to EPO. DMERCs shall accept claims for Aranesp, Q4054, from suppliers that bill for Aranesp furnished to home patients for self-administration who have elected home dialysis and Method II payment.

DMERCs must accept HCPCS code Q4054 for Aranesp on the CMS-1500 or its electronic equivalent 837 P format. The DMERC shall return to provider (RTP) assigned claims for claims for Aranesp, Q4054, that do not contain a HCT value. For unassigned claims, the DMERC shall deny claims for Aranesp, Q4054, that do not contain a HCT value.

Method II suppliers must place number of mcg’s of Aranesp Q4054 administered in Item Field 24G Units on the CMS- 1500 form, or 2400 SV104 of the 837P format. Method II suppliers must use Item 19 on the CMS 1500 to place the most current HCT value (Q4054). Identify HCT as “HCT = the true value HCT”. For 837P claims, the Method II supplier must supply the most current HCT value, when billing for Aranesp Q4054, in the 2400 MEA03 with a qualifier of R2 in 2400 MEA02.

DMERCs must use the following messages when payment for the Aranesp injection (Q4054) does not meet the coverage criteria and is denied:

MSN Message 6.5—English: Medicare cannot pay for this injection because one or more requirements for coverage were not met

MSN Message 6.5—Spanish: Medicare no puede pagar por esta inyección porque uno o más requisitos para la cubierta no fueron cumplidos. (MSN Message 6.5 in Spanish).

Adjustment Reason Code B:5 Payment adjusted because coverage/program guidelines were not met or were exceeded.

The DMERCs shall use the following messages when returning as unprocessable assigned claims without a HCT value:

ANSI Reason Code 16 – Claim/service lacks information, which is needed for adjudication.

Additional information is supplied using remittance advice remarks codes whenever appropriate.

Remark Code M58 – Missing/incomplete/invalid claim information. Resubmit claim after corrections.

Deductibles and coinsurance apply. DMERCs must pay for Aranesp (Q4054) based on the payment amount in the MMA Drug Payment Limits Pricing File. The contractor can obtain the rates from the CMS website, www.cms.hhs.gov/providers/drugs/default.asp.

60.7.2.1- Other Information Required on the Form CMS-1500 for Darbepoetin Alfa (Aranesp)

(Rev 118, 03-05-04)

The following information is required for Aranesp. Incomplete assigned claims are returned to providers for completion. Incomplete unassigned claims are rejected. The rejection will be due to a lack of a HCT value. Note that when a claim is submitted on paper Form CMS-1500, these items are submitted on a separate document. It is not necessary to enter them into the claims processing system. This information is used in utilization review.

- A. Diagnoses - The diagnoses must be submitted according to ICD-9-CM and correlated to the procedure. This information is in Item 21, of the Form CMS-1500.***
- B. Date of the Patient's most recent HCT.***
- C. Most recent HCT (prior to initiation of Aranesp therapy).***
- D. Date of most recent HCT (prior to initiation of Aranesp therapy).***
- F. Patient's most recent serum creatinine - (within the last month, prior to initiation of Aranesp therapy).***

- G. Date of most recent serum creatinine - (prior to initiation of Aranesp therapy).*
- H. Patient's weight in kilograms*
- I. Patient's starting dose per kilogram*

60.7.2.2- Completion of Subsequent Form CMS-1500 Claims for Darbepoetin Alfa (Aranesp)

(Rev 118, 03-05-04)

Subsequent claims are completed as initial claims in §60.7.2, except the following fields:

- A. Diagnoses.*
- B. Hematocrit – For dates of service prior to January 1, 2004, this is indicated by the appropriate Q code. For dates of service January 1, 2004 and after, suppliers must indicate the beneficiary's hematocrit on the claim. (See 60.7.2). Claims include an EJ modifier to the Q code. This allows the contractor to identify subsequent claims, which do not require as much information as initial claims and prevent unnecessary development.*
- C. Number of Units Administered - Subsequent claims may be submitted electronically.*

60.7.3 - Payment Amount for Darbepoetin Alfa (Aranesp)

(Rev 118, 03-05-04)

For Method I patients, the FI pays the facility per one mcg of Aranesp administered, in accordance with the MMA Drug Payment Limits Pricing File rounded up to the next highest whole mcg. When Aranesp is furnished by a supplier that is not a facility, the DMERC pays at the same rate. The payment amount for Aranesp is the only payment for the drug and its administration.

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

The coinsurance and deductible are based on the Medicare allowance payable, not on the provider's charges. The provider may not charge the beneficiary more than 20 percent of the Medicare Aranesp allowance. This rule applies to independent and hospital based **renal** facilities.

60.7.3.1 - Payment for Darbepoetin Alfa (Aranesp) in Other Settings

(Rev 118, 03-05-04)

In the hospital inpatient setting, payment for Aranesp is included in the DRG.

In a skilled nursing facility (SNF), payment for Aranesp covered under the Part B EPO benefit is not included in the prospective payment rate for the resident's Medicare-covered SNF stay.

In a hospice, payment is included in the hospice per diem rate.

For a service furnished by a physician or incident to a physician's service, payment is made to the physician by the carrier in accordance with the rules for "incident to" services. When Aranesp is administered in the renal facility, the service is not an "incident to" service and not under the "incident to" provision.

60.7.3.2 - Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department

(Rev 118, 03-05-04)

For patients with chronic renal failure who are not yet on a regular course of dialysis, Aranesp administered in a hospital outpatient department is paid under the OPPS.

Hospitals use bill type 13X and report charges under revenue code 0636, with HCPCS code Q0137 and without value codes 48, 49, 68 or condition codes 70-76.

60.7.4 – Darbepoetin Alfa (Aranesp) Furnished to Home Patients

(Rev 118, 03-05-04)

B3-4270.1

Medicare covers Aranesp for dialysis patients who use Aranesp in the home, when requirements for a patient care plan and patient selection as described in the Medicare Benefit Policy Manual, Chapter 11, are met.

When Aranesp is prescribed for a home patient, it may be either administered in a facility, e.g., the one shown on the Form CMS-382 (ESRD Beneficiary Method Selection Form) or furnished by a facility or Method II supplier for self-administration to a home patient determined to be competent to administer this drug. For Aranesp furnished for self-administration to Method I and Method II home patients determined to be competent, the renal facility bills its FI and the Method II supplier bills its DMERC. No additional payment is made for training a prospective self-administering patient or retraining an existing home patient to self-administer Aranesp.

Method II home patients who self-administer may obtain Aranesp only from either their Method II supplier or a Medicare-certified ESRD facility.

In this case, the DMERC makes payment at the same rate that applies to facilities. Program payment may not be made for Aranesp furnished by a physician to a patient for self-administration.

