

---

# CMS Manual System

## Pub. 100-20 One-Time Notification

---

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

Transmittal 39

Date: JANUARY 6, 2004

---

CHANGE REQUEST 2963

**This transmittal replaces transmittal 18. The only change to this transmittal is that it is no longer a Confidential Requirement and can now be posted to the Internet or Intranet. All other material remains the same.**

**I. SUMMARY OF CHANGES:** This one-time notification contains coding instructions for administration of darbepoetin alfa (Aranesp) for End Stage Renal Disease patients on dialysis received on or after January 1, 2004. This notification also lists a new HCPCS code for EPO and deletes all the current "Q" codes established for EPO.

**NEW MATERIAL - EFFECTIVE DATE: January 1, 2004**

**\*IMPLEMENTATION DATE: January 5, 2004**

**II. CHANGES IN MANUAL INSTRUCTIONS: N/A**

**III. FUNDING: \*Medicare contractors only:**

**These instructions should be implemented within your current operating budget.**

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
<b>X</b>	<b>One-Time Notification</b>

*This One-Time Notification replaces Transmittal 18, originally a Confidential Requirement. The only change to this transmittal is that it is no longer a Confidential Requirement and can now be posted to the Internet or Intranet. All other information remains the same.*

## One-Time Notification

Pub. 100-20	Transmittal: 39	Date: January 6, 2004	Change Request: 2963
-------------	-----------------	-----------------------	----------------------

**SUBJECT: 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.**

### I. GENERAL INFORMATION

Upon investigation by CMS, it was discovered that revenue codes and value codes are being used by Fiscal Intermediaries (FIs) for billing EPO usage rather than the assigned Q codes (Q9920 through Q9940). Therefore, these Q codes for EPO will be rescinded, and the renal providers will no longer be able to use these codes for services furnished on or after January 1, 2004. A new HCPCS code is provided for End Stage Renal Disease (ESRD) EPO usage only. All other rules still apply for billing EPO for ESRD related anemia.

Currently, there is no code that specifically identifies usage for Darbepoetin Alfa (trade name Aranesp) for ESRD. As a result, CMS is establishing a new HCPCS code for ESRD Aranesp usage only. This new code, Q4054, will take affect for services provided on or after January 1, 2004.

**NOTE:** Due to the extension of the use of the NSF format, all carriers and DMERC business requirements must be extended to the NSF format as well as the 837 P formats. Due to the extension of the use of the UB92 6.0 format, all FIs business requirements must be extended to the UB92 6.0 format as well as the 837 I format. The contractors need to update their Free Billing Software to be able to accept Hematocrit levels.

#### A. Background

This notification contains coding instructions for administration of darbepoetin alfa (Aranesp) for ESRD patients on dialysis received on or after January 1, 2004. This notification also list a new HCPCS code for EPO and deletes all the current "Q" codes established for EPO. In addition, code J0880 will no longer be paid by Medicare effective January 1, 2004. Since there is currently no payment rate for Darbepoetin alfa, CMS has determined that code Q4054 should be paid based on the Single Drug Pricer payment amount. This payment rate will be in effect until CMS has determined an appropriate conversion factor and corresponding payment rate for Darbepoetin alfa.

**B. Policy:**

All ESRD hematocrit (Hct) linked published Q codes for epoetin alfa have been deleted (Q9920 through Q9940) and replaced with **Q4055**.

**(new) Q4054 Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)**

Medicare jurisdiction: DME regional carrier when self-administered for Method II home patients; FI when self-administered for Method I or Method II home patients, when administered by the hospital outpatient department, when administered to infacility patients by the dialysis facility; and carrier when incident to a physician’s service. Use this code for darbepoetin alfa (Aranesp).

**(new) Q4055 Injection, epoetin alfa. 1,000 units (for ESRD on dialysis)**

Medicare jurisdiction: DME regional carrier when self-administered for Method II home patients; FI when self-administered for Method I or Method II home patients, when administered by the hospital outpatient department, when administered to infacility patients by the dialysis facility; and carrier when incident to a physician’s service. Use this code for Epoetin Alfa (Epogen, EPO).

**C. Provider Education:** Intermediaries and carriers shall inform affected providers by posting either a summary or relevant portions of this document on their Web site within two weeks. Also, intermediaries and carriers shall publish this same information in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers that information about Darbepoetin Alfa (trade name Aranesp) for treatment of anemia in ESRD patients on dialysis and Epoetin Alfa (trade name Epogen, EPO) for the treatment of anemia in ESRD patients on dialysis is available on their Web site.

**II. BUSINESS REQUIREMENTS**

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

<b>Requirement #</b>	<b>Requirements</b>	<b>Responsibility</b>
2963.1	Medicare contractors shall cover darbepoetin alfa in the same manner as epoetin alfa.	FI, Carrier DMERC & SSM
2963.2	The FI shall accept claims for darbepoetin alfa, Q4054, when billed on Form CMS-1450 or its electronic equivalent 837I.	FI & SSM
2963.2.1	The FI shall make payment for darbepoetin alfa, Q4054, per mcg. For doses that are more than a whole mcg: the FI shall advise the provider to round up to the next whole mcg for billing purposes.	FI & SSM
2963.2.2	The FI shall accept darbepoetin alfa, Q4054, as a line item per administration with the line item date of service and the number of mcg’s in the units form locator on Form CMS-1450 or its electronic equivalent 837I.	FI & SSM

2963.3	The FI shall accept darbepoetin alfa, Q4054, claims from Freestanding ESRD Facilities submitted on a 72x type of bill with HCPCS and revenue code 0636 (2400 SV201 on the ANSI 837I HIPAA transaction).	FI & SSM
2963.3.1	The FI shall pay for darbepoetin alfa, Q4054, claims to a Freestanding ESRD Facility (facilities that are not classified as hospital-based), submitted on a 72x type of bill with revenue code 0636 (2400 SV201 on the ANSI 837I HIPAA transaction) and with HCPCS code Q4054 as an add-on payment to the composite rate.	FI & SSM
2963.4	The FI shall accept darbepoetin alfa, Q4054, claims from Hospital-based ESRD Facilities submitted on a 72x type of bill with revenue code 0636 (2400 SV201 on the ANSI 837I HIPAA transaction).	FI & SSM
2963.4.1	The FI shall pay for darbepoetin alfa, Q4054, claims to a Hospital-based ESRD Facility, submitted on a 72x type of bill with revenue code 0636 (2400 SV201 on the ANSI 837I HIPAA transaction) and HCPCS code Q4054, as an add-on payment to the composite rate.	FI & SSM
2963.5	DMERC shall accept claims for darbepoetin alfa, Q4054, from suppliers that bill for darbepoetin alfa supplies furnished to home patients for self-administration who have elected home dialysis and Method II payment.	DMERC
2963.5.1	DMERC shall make payment for darbepoetin alfa, Q4054, to suppliers that bill for darbepoetin alfa supplies furnished to home patients for self-administration who have elected home dialysis and Method II payment.	DMERC
2963.5.2	DMERC's and Standard Systems Maintainers must accept HCPCS code Q4054 for darbepoetin alfa on Form CMS-1500 or its electronic equivalent 837 P format.	DMERC & SSM
2963.6	The carrier shall accept claims for darbepoetin alfa when billed incident to a physician's service with the appropriate HCPCS code Q4054.	Carrier & SSM
2963.6.1	The carrier shall make payment for darbepoetin alfa, Q4054, when billed incident to a physician's service in accordance with the usual established single drug pricer (SDP) instructions applicable to drugs furnished incident to a physician's service. (See PMs AB-02-174, AB-03-014, AB-03-047).	Carrier & SSM
2963.6.2	The carrier shall make payment for darbepoetin alfa, Q4054, per mcg. For doses that are more than a whole mcg: the carrier shall advise the provider to round up to the next whole mcg for billing purposes.	Carrier & SSM
2963.6.3	The Medicare contractor shall apply the Medicare Part B deductible to darbepoetin alfa payments, HCPCS code Q4054.	FI, Carrier DMERC & SSM
2963.6.4	The Medicare contractor shall apply the Medicare Part B coinsurance to darbepoetin alfa payments, HCPCS code Q4054.	FI, Carrier DMERC & SSM

2963.7	The carrier shall accept claims for epoetin alfa, Q4055, when billed incident to a physician's service with the appropriate HCPCS code Q4055.	Carrier & SSM
2963.7.1	The carrier shall make payment for epoetin alfa, Q4055, when billed incident to a physician's service in accordance with the usual established single drug pricer (SDP) instructions applicable to drugs furnished incident to a physician's service. (See PMs AB-02-174, AB-03-014, AB-03-047).	Carrier & SSM
2963.7.2	The Medicare contractor shall apply the Medicare Part B deductible requirements to epoetin alfa payments, HCPCS code Q4055.	FI, Carrier DMERC & SSM
2963.7.3	The Medicare contractor shall apply Medicare Part B coinsurance to epoetin alfa payments, HCPCS code Q4055.	FI, Carrier DMERC & SSM
2963.7.4	The Medicare contractor shall continue to pay the statutory rate for Epoetin Alfa (Q4055) at \$10.00 per 1000 units.	FI, DMERC, and SSM
2963.7.5	The Medicare contractor shall pay for Darbepoetin alfa (Q4054) based on the Single Drug Pricer payment amount. The contractor can obtain the SDP rates from the CMS Web site, <a href="http://www.cms.hhs.gov/providers/drugs/default.asp">www.cms.hhs.gov/providers/drugs/default.asp</a> .	FI, DMERC and SSM
2963.8	The FI shall return to provider all claims for epoetin alfa, Q4055, and darbepoetin alfa, Q4054, with value code 49 (2300 HI01-2 with the qualifier of BE in 2300 HI01-1 on the ANSI 837I HIPAA transaction) and no hematocrit (Hct) reading taken prior to the last administration of epoetin alfa or darbepoetin alfa during the billing period.	FI & SSM
2963.8.1	The FI shall return to provider all claims for epoetin alfa, Q4055, with value code 48 (2300 HI01-2 with the qualifier of BE in 2300 HI01-1 on the ANSI 837I HIPAA transaction) and no Hemoglobin (Hgb) reading taken prior to the last administration of epoetin alfa during the billing period.	FI & SSM
2963.9	The DMERC shall return to provider (RTP) claims for epoetin alfa, Q4055, that do not contain a Hct value and claims for darbepoetin alfa, Q4054, that do not contain a Hct value.	DMERC & SSM
2963.9.1	The DMERC standard system shall implement edits to return as unprocessable assigned 837 electronic claims for epoetin alfa, Q4055, or darbepoetin alfa, Q4054, that do not contain a Hct value.	DMERC & SSM
2963.9.1.1	The DMERCs shall return as unprocessable assigned paper claims for epoetin alfa, Q4055, or darbepoetin alfa, Q4054, that do not contain a Hct value.	DMERC & SSM
2963.9.1.2	The DMERCs shall deny unassigned 837 electronic claims for epoetin alfa, Q4055, or darbepoetin alfa, Q4054, that do not contain a Hct value.	DMERC & SSM

2963.9.1.3	The DMERCs shall deny unassigned paper claims for epoetin alfa, Q4055, or darbepoetin alfa, Q4054, that do not contain a Hct value.	DMERC & SSM
2963.9.2	The standard system shall provide carriers with claims editing capability for epoetin alfa, Q4055, or darbepoetin alfa, Q4054, that do not contain a Hct value.	Carrier & SSM (but not DMERC)
2963.9.3	The Medicare contractor shall deny claims for epoetin alfa, Q4055, or darbepoetin alfa, Q4054, that do not contain a Hct value. For ANSI 837 transactions, the Hct value is reported in 2400 MEA03 with a qualifier of R2 in 2400 MEA02. The denial will be a denial due to lack of documentation.	Carrier & SSM (but not DMERC)
2963.9.4	The standard system shall provide edit capability to systematically reject claims to the DMERCs for epoetin alfa, Q4055, or darbepoetin alfa, Q4054, that do not contain a Hct value in 2400 MEA03 with a qualifier of R2 in 2400 MEA02 on the ANSI 837P HIPAA transaction. This applies to assigned claims.	SSM & DMERC
2963.10	The number of units of epoetin alfa, Q4055, administered will be placed in Item Field 24G <i>Units</i> on Form CMS- 1500.	Carrier DMERC & SSM
2963.10.1	The number of units of epoetin alfa, Q4055, administered will be placed in 2400 SV104.	Carrier, DMERC & SSM
2963.10.2	The provider or supplier shall use HCPCS code, Q4055, for billing for epoetin alfa when using Medicare Type 2 billing to the DMERC's.	DMERC & SSM
2963.10.3	The DMERC provider shall use Item Field 19 on Form CMS 1500 to place the most current Hct value (Q4055). Identify Hct as "Hct = the true value Hct".	DMERC & SSM
2963.10.4	The DMERC provider or supplier must supply the most current Hct value (Q4055), when billing for epoetin alfa, in the 2400 MEA03 with a qualifier of R2 in 2400 MEA02 on the ANSI 837P HIPAA transaction.	DMERC & SSM
2963.11	The number of mcg's of darbepoetin alfa Q4054 administered will be placed in Item Field 24G <i>Units</i> on Form CMS- 1500.	Carrier, DMERC & SSM
2963.11.1	The number of mcg's of darbepoetin alfa Q4054 administered will be placed in 2400 SV104.	Carrier, DMERC & SSM
2963.11.2	The provider or supplier shall use HCPCS code Q4054 for billing for darbepoetin alfa when using Medicare Type 2 billing by the DMERC's.	DMERC & SSM
2963.11.3	The DMERC provider shall use Item 19 on Form CMS 1500 to place the most current Hct value (Q4054). Identify Hct as "Hct = the true value Hct".	DMERC & SSM

2963.11.4	The DMERC provider or 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 on the ANSI 837P HIPAA transaction.	DMERC & SSM
2963.12	The provider or supplier shall continue to bill under bill type 72x for epoetin alfa in the same manner using HCPCS code Q4055 along with revenue code 0634 ( <i>2400 SV201 on the ANSI 837I HIPAA transaction</i> ) for administration of under 10,000 units of EPO or revenue code 0635 ( <i>2400 SV201 on the ANSI 837I HIPAA transaction</i> ) for administration of over 10,000 units of EPO.	FI & SSM
2963.12.1	The provider or supplier shall continue to bill under bill type 72x for epoetin alfa Q4055 using value codes 48 or 49 ( <i>2300 HI01-2 with the qualifier of BE in 2300 HI01-1 on the ANSI 837I HIPAA transaction</i> ) to record Hct or Hgb values.	FI & SSM
2963.12.2	The provider or supplier shall continue to bill for epoetin alfa Q4055 using value code 68 ( <i>2300 HI01-2 with the qualifier of BE in 2300 HI01-1 on the ANSI 837I HIPAA transaction</i> ) to report the number of units of EPO administered during the billing period	FI & SSM
2963.12.3	The Medicare contractor shall not make payment to a physician for epoetin alfa for self-administration.	Carrier, DMERC & SSM
2963.12.4	The supplier or provider shall use Item 19 on Form CMS 1500 to place the most current Hct value.	Carrier, DMERC & SSM
2963.12.5	The carrier or DMERC shall verify the format of the Hct in Item 19 of Form CMS-1500 or its electronic equivalent 837 P format.	Carrier, DMERC & SSM
2963.13	The Medicare contractor shall use the following Medicare Summary Notice (MSN) when payment for the injection (Q4054, Q4055) does not meet the coverage criteria and is denied.  Medicare cannot pay for this injection because one or more requirements for coverage were not met. (MSN Message 6.5) or  Medicare no puede pagar por esta inyeccion porque uno o mas requisitos para la cubierta no fueron cumplidos. (MSN Message 6.5 in Spanish).	FI, Carrier, & SSM (not DMERC)
2963.13.1	The Medicare contractor shall use Adjustment Reason Code B5 when MSN Message 6.5 is used for denial of Q4054 or Q4055. Payment adjusted because coverage/program guidelines were not met or were exceeded.	FI, Carrier, & SSM (not DMERC)
2963.13.2	The DMERCs shall use the following messages when returning as unprocessable assigned claims without a Hct value:	DMERC & SSM

	<p>ANSI Reason Code 16 – Claim/service lacks information which is needed for adjudication.</p> <p>Additional information is supplied using remittance advice remarks codes whenever appropriate.</p> <p>Remark Code M58 – Missing/incomplete/invalid claim information. Resubmit claim after corrections.</p>	
2963.13.3	<p>The DMERCs shall use the following messages when denying unassigned claims without a Hgb value:</p> <p>ANSI Reason Code 16 – Claim/service lacks information which is needed for adjudication.</p> <p>Additional information is supplied using remittance advice remarks codes whenever appropriate.</p> <p>Remark Code M58 – Missing/incomplete/invalid claim information. Resubmit claim after corrections.</p> <p>MSN Message 9.02 – This item or service was denied because information required to make payment is missing.</p>	DMERC & SSM
2963.14	The type of service (TOS) for the new “Q” codes is I, L.	Carrier, DMERC & CWF
2963.14.1	The Medicare contractor shall not make payment to a physician for darbepoetin alfa, Q4054, for self-administration.	Carrier, DMERC & SSM
2963.15	The Medicare contractor shall notify providers and suppliers of coding for darbepoetin alfa, Q4054, and epoetin alfa, Q4055, in the contractor’s next regularly scheduled bulletin.	FI, Carrier & DMERC
2963.15.1	The Medicare contractor shall notify providers and suppliers of coding for darbepoetin alfa, Q4054, and epoetin alfa, Q4055, in the contractor’s Web site within 4 weeks of receiving this instruction.	FI, Carrier & DMERC
2963.15.2	The Medicare contractor shall notify providers and suppliers of coding for darbepoetin alfa, Q4054, and epoetin alfa, Q4055, in the contractor’s next routinely scheduled training sessions.	FI, Carrier & DMERC
2963.15.3	The Medicare contractor shall use their listserv to notify the affected provider community that information about “Coding for darbepoetin alfa, Q4054,” is available on the contractor’s Web site.	FI, Carrier, DMERC & SSM
2963.15.4	The Medicare contractor shall notify providers and suppliers of the deletion of Q codes and the new replacement code for epoetin alfa, Q4055, usage in their next regularly scheduled bulletin, training sessions, and Web site.	FI, Carrier, DMERC & SSM
2963.15.5	The Medicare contractor shall notify providers and suppliers of billing changes for epoetin alfa, Q4055, usage in their next regularly scheduled bulletin, training sessions and Web site.	FI, Carrier, DMERC, & SSM



### III. SUPPORTING INFORMATION & POSSIBLE DESIGN CONSIDERATIONS

#### A. Other Instructions:

X-Ref Requirement #	Instructions
2963.2	The FI shall apply general claims processing instructions for Form CMS-1450 or its electronic equivalent from the Medicare Intermediary Manual (MIM) Part 3, 3604.
2963.8	The carrier shall apply general claims processing instructions for Form CMS-1500 or its electronic equivalent from the Medicare Carrier Manual (MCM) Part 4, Chapter 2.

#### B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements
	Coverage rules for darbepoetin alfa are the same as epoetin alfa for ESRD related anemia.

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