CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2582	**Date: November 2, 2012**
	Change Request 8050

SUBJECT: New Erythropoietin Stimulating Agent (ESA) Peginesatide Requirements for End Stage Renal Disease (ESRD)

I. SUMMARY OF CHANGES: Peginesatide drug added to drugs subject to the ESRD ESA billing requirements, including the ESRD ESA claims monitoring policy. In addition, some sections of the manual are rearranged but their content remains largely the same. Specifically, method II information is being moved but retained only for historical information. Darbepoetin Alfa (Aranesp) is being moved from section 60.7 to section 60.4.6.

EFFECTIVE DATE: April 1, 2013
IMPLEMENTATION DATE: April 1, 2013

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/ Table of Contents
R	8/50.9 Coding for Adequacy of Dialysis, Vascular Access and Infection
R	8/60.1 Lab Services
R	8/60.3 Blood and Blood Services Furnished in Hospital Based and Independent Dialysis Facilities
D	8/ 60.2.3.1 - Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs
R	8/ 60.4 - Erythropoietin Stimulating Agents (ESAs)
R	8/ 60.4.1 - ESA Claims Monitoring Policy
R	8/ 60.4.2 - Facility Billing Requirements for ESAs
R	8/ 60.4.3 - Epoetin Alfa (EPO) Supplier Billing Requirements (Method II) on the Form CMS-1500
R	8/ 60.4.3.1 - Other Information Required on the Form CMS-1500 for Epoetin Alfa (EPO)
R	8/ 60.4.3.2 - Completion of Subsequent Form CMS-1500 Claims for Epoetin Alfa (EPO)
R	8/ 60.4.4 - Payment Amount for Epoetin Alfa (EPO)
R	8/ 60.4.4.1 - Payment for Epoetin Alfa (EPO) in Other Settings
N	8/ 60.4.4.2 - Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments
N	8/ 60.4.5 - ESAs Furnished to Home Patients
N	8/ 60.4.5.1 - Self Administered ESA Supply
N	8/ 60.4.6 - Darbepoetin Alfa (Aranesp) Supplier Billing Requirements (Method II) on the Form CMS-1500 and Electronic Equivalent
N	8/ 60.4.6.1 - Other Information Required on the Form CMS-1500 for Darbepoetin Alfa (Aranesp)
N	8/ 60.4.6.2 - Completion of Subsequent Form CMS-1500 Claims for Darbepoetin Alfa (Aranesp)
N	8/ 60.4.6.3 - Payment for Darbepoetin Alfa (Aranesp)
N	8/ 60.4.6.4 - Payment for Darbepoeti Alfa (Aranesp) in Other Settings
N	8/ 60.4.6.5 - Payment for Darbepoetin Alf (Aranesp) in the Hospital Outpatient Department
R	8/ 60.7 Reserved
D	8/ 60.7.1 - Darbepoetin Alfa (Aranesp) Facility Billing Requirements
D	8/ 60.7.2 Darbepoetin Alfa (Aranesp) Supplier Billing Requirements (Method II) on the Form CMS-1500 and Electronic Equivalent

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
D	8/ 60.7.2.1 Other Information Required on the Form CMS-1500 for Darbepoetin Alfa (Aranesp)
D	8/ 60.7.2.2 Completion of Subsequent Form CMS-1500 Claims for Darbepoetin Alfa (Aranesp)
D	8/ 60.7.3 Payment for Darbepoetin Alfa (Aranesp)
D	8/ 60.7.3.1 Payment for Darbepoetin Alfa (Aranesp) in Other Settings
D	8/ 60.7.3.2 Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department
D	8/ 60.7.4 - Darbepoetin Alfa (Aranesp) Furnished to Home Patients

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

For Medicare Administrative Contractors (MACs):
The Medicare Administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged 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.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 2582	November 2, 2012	Change Request: 8050

SUBJECT: New Erythropoietin Stimulating Agent (ESA) Peginesatide Requirements for End Stage Renal Disease (ESRD)

EFFECTIVE DATE: April 1, 2013

IMPLEMENTATION DATE: April 1, 2013

I. GENERAL INFORMATION

A. Background: Peginesatide is a new ESA drug approved for the treatment of anemia in dialysis patients. Effective January 1, 2013, Peginesatide is assigned a permanent Healthcare Common Procedure Code System (HCPCS) code J0890. This permanent code replaces the temporary code Q2047. Peginesatide is an ESA and therefore, is subject to the claim requirements and system edits implemented with the national claims monitoring policy (i.e. monitoring policy) for ESAs. Medicare implemented the monitoring policy for ESAs administered in Medicare ESRD facilities effective April 1, 2006. While the monitoring policy and its applicable payment adjustments are not applied to home dialysis patients, other claim requirements applicable to billing ESAs are required for all ESRD claims. The complete policy is available at Publication 100-4, Chapter 8, Section 60.4.

B. Policy: Peginesatide billed with HCPCS J0890 is subject to the national ESA claims monitoring program for ESRD claims with dates of service on or after April 1, 2013. Peginesatide is allowable once per monthly billing cycle. Claims containing more than once per billing cycle will be returned to the provider. Claims reporting dosages equal to or greater than 26 mg within a 30 / 31 day billing period are considered likely typographical errors and will be returned to the provider for correction. As with other ESAs, the consolidated billing edit for peginesatide will be overridden for outpatient hospital claims billing for an emergency or unscheduled dialysis session.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement.

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8050.1	Contractors shall recognize new HCPCS J0890 for ESRD TOB 72x with dates of service on or after January 1, 2013.	X			X			X				IOCE
8050.2	For dates of service on or after April 1, 2013, Medicare contractors shall return TOB 72x claims to the provider containing J0890 and value code 48 and or value code 49 contain the default value of 99.99.	X			X			X				

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8050.3	For dates of service on or after April 1, 2013, Medicare contractors shall return claims to the provider when a history or incoming claim contains more than 1 administration per month (i.e. more than 1 line item) of J0890 except when the claim is for home dialysis treatments and contains only 2 administrations with condition code 70 (self-administration) and one of the line item administrations includes modifier EM "emergency reserve supply".	X			X			X				
8050.4	For dates of service on or after April 1, 2013, Medicare contractors shall return TOB 72x claims to the provider when the claim contains J0890 without reporting the route of administration modifier (JA or JB) on each line item reporting the drug.	X			X			X				
8050.5	For dates of service on or after April 1, 2013, Medicare contractors shall return TOB 72x claims to the provider that contain a total units billed for J0890 equal to or greater than 26 mg.	X			X			X				
8050.6	For dates of service on or after April 1, 2013, Medicare contractors shall return TOB 72x claims for in-facility dialysis to the provider when the value code 48 exceeds 13 or the value code 49 exceeds 39 and modifier ED or EE is not present on the J0890 line item.	X			X			X				
8050.7	For dates of service on or after April 1, 2013, Medicare contractors shall apply a 25% reduction to the payment on the TOB 72x claims for in-facility dialysis when the modifier EE is present on the J0890 line item and modifier GS is **not**appended to one of the claim lines containing J0890. This reduction is not applied when modifier GS is present. Note: This payment reduction is applied to the separately billable payment for providers transitioning into the ESRD PPS and is applied the Medicare allowed payment (MAP) amount for the outlier consideration (value code 79) for the PPS payment.	X			X			X				
8050.7.1	Medicare contractors shall apply provider liability (Remark code CO) when occurrence code 32 or modifier GA is not present.	X			X			X				

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8050.7.2	Medicare contractors shall apply beneficiary liability (Remark code PR) when occurrence code 32 or modifier GA is present.	X			X			X				
8050.8	For dates of service on or after April 1, 2013, Medicare contractors shall apply a 50% reduction to the payment on the TOB 72x claims for in-facility dialysis when the modifier ED is present on the J0890 line item, regardless of the presence of modifier GS. Note: This payment reduction is applied to the separately billable payment for providers transitioning into the ESRD PPS and is applied to the Medicare allowed payment (MAP) amount for the outlier consideration (value code 79) for the PPS payment.	X			X			X				
8050.8.1	Medicare contractors shall apply provider liability (Remark code CO) when occurrence code 32 or modifier GA is not present.Medicare contractors shall apply provider liability (Remark code CO) when occurrence code 32 or modifier GA is not present.	X			X			X				
8050.8.2	Medicare contractors shall apply beneficiary liability (Remark code PR) when occurrence code 32 or modifier GA is present.	X			X			X				
8050.8.3	Medicare contractors shall notify providers of reduction in payment with adjustment reason code 153 – Payment adjusted because the payer deems the information submitted does not support this dosage.	X			X			X				
8050.8.4	Medicare contractors shall notify beneficiaries of the reduction in payment with MSN code 15.15 – Payment has been reduced because information provided does not support the need for this item as billed.	X			X			X				
8050.9	Medicare contractors shall override the ESRD PPS consolidated billing edit for bill types 13x and 85x when J0890 is billed with G0257.	X			X			X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Other
		Part A	Part B					
8050.10	MLN Article : A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites 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 the contractor's 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

Section A: Recommendations and supporting information associated with listed requirements:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	All requirements are consistent with existing ESA billing policies already in effective for Epoetin (Q4081) and Aranesp (J0882). FISS shall update existing edits to include the requirements in this instruction for J0890.

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): NA NA, 123-456-7890 (Converted CR contact) , Wendy Tucker, wendy.tucker@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

Section B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. 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.

Medicare Claims Processing Manual

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

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(Rev. 2582, 11-02-12)

50.9 - Coding for Adequacy of Dialysis, Vascular Access and Infection

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

A. Reporting the Urea Reduction Ratio(URR) for ESRD Hemodialysis Claims

All hemodialysis claims must indicate the most recent Urea Reduction Ratio (URR) for the dialysis patient. Code all claims using HCPCS code 90999 along with the appropriate G modifier listed in section B.

Claims for dialysis treatments must include the adequacy of hemodialysis data as measured by URR. Dialysis facilities must monitor the adequacy of dialysis treatments monthly for facility patients. Home hemodialysis and peritoneal dialysis patients may be monitored less frequently, but not less than quarterly. If a home hemodialysis patient is not monitored during a month, the last, most recent URR for the dialysis patient must be reported.

HCPCS code 90999 (unlisted dialysis procedure, inpatient or outpatient) must be reported in field location 44 for all bill types 72X. The appropriate G-modifier in field location 44 (HCPCS/RATES) is used, for patients that received seven or more dialysis treatments in a month. Continue to report revenue codes 0820, 0821, 0825, and 0829 in field location 43.

G1 - Most recent URR of less than 60%
G2 - Most recent URR of 60% to 64.9%
G3 - Most recent URR of 65% to 69.9%
G4 - Most recent URR of 70% to 74.9%
G5 - Most recent URR of 75% or greater

For patients that have received dialysis 6 days or less in a month, facilities use the following modifier:

G6 - ESRD patient for whom less than seven dialysis sessions have been provided in a month.

For services beginning January 1, 2003, and after, if the modifier is not present, FIs must return the claim to the provider for the appropriate modifier. Effective April, 2007 due to the requirement of line item billing, at least one revenue code line for hemodialysis on the claim must contain one of the URR modifiers shown above. The URR modifier is not required on every hemodialysis line on the claim.

The techniques to be used to draw the pre- and post-dialysis blood urea Nitrogen samples are listed in the National Kidney Foundation Dialysis Outcomes Quality Initiative Clinical Practice Guidelines for Hemodialysis Adequacy, Guideline 8, Acceptable Methods for BUN sampling, New York, National Kidney Foundation, 2000, pp.53-60.

B. Reporting the Vascular Access for ESRD Hemodialysis Claims

ESRD claims for hemodialysis with dates of service on or after July 1, 2010 must indicate the type of vascular access used for the delivery of the hemodialysis at the last hemodialysis session of the month. One of the following codes is required to be reported on the latest line item date of service billing for hemodialysis revenue code 0821. It may be reported on all revenue code 0821 lines at the discretion of the provider.

Note: Modifier V5 must be entered if a vascular catheter is present even if it is not being used for the delivery of the hemodialysis. In this instance 2 modifiers should be entered, V5 for the vascular catheter and either V6 or V7 for the access that is being used for the delivery of hemodialysis.

Modifier V5 - Any Vascular Catheter (alone or with any other vascular access),

Modifier V6 - Arteriovenous Graft (or other Vascular Access not including a vascular catheter in use with two needles)

Modifier V7 - Arteriovenous Fistula Only (in use with two needles)

C. Reporting the Kt/V for ALL ESRD Claims

All ESRD claims with dates of service on or after July 1, 2010 must indicate the applicable Kt/V reading for the dialysis patient. The reading result and the date of the reading must be reported on the claim using the following claim codes:

Value Code D5 – Result of last Kt/V reading. For in-center hemodialysis patients this is the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis this may be before the current billing period but should be within 4 months of the claim date of service.

- **Hemodialysis:** For in-center and home-hemodialysis patients prescribed for three or fewer treatments per week, the last Kt/V obtained during the month must be reported. Facilities must report single pool Kt/V using the preferred National Quality Forum (NQF) endorsed methods for deriving the single pool Kt/V value: Daugirdas II or Urea Kinetic Modeling (UKM). The reported Kt/V should not include residual renal function.

A value of 8.88 shall be entered on the claim if the situation exists that a patient is prescribed and receiving greater than three hemodialysis treatments per week for a medically justified and documented clinical need. The 8.88 value is not to be used for patients who are receiving "extra" treatments for a temporary clinical need (e.g. fluid overload). A medical justification must be submitted for patients receiving greater than 13 treatments per month.

- **Peritoneal Dialysis**: When measured the delivered weekly total Kt/V (dialytic and residual) should be reported.

This code is effective and required on all ESRD claims with dates of service on or after July 1, 2010. In the event that no Kt/V reading was performed providers must report the D5 with a value of 9.99.

Occurrence Code 51 – Date of last Kt/V reading. For in-center hemodialysis patients, this is the date of the last reading taken during the billing period. For peritoneal dialysis patients and home hemodialysis patients, this date may be before the current billing period but should be within 4 months of the claim date of service. This code is effective for ESRD claims with dates of service on or after July 1, 2010. This code not required when reporting value code D5 with a value of 9.99 indicating no Kt/V reading is available for reporting or value 8.88 to indicate the patient is prescribed and receiving greater than 3 hemodialysis treatments per week for a medically justified and documented clinical need.

D. Reporting of Infection for ALL ESRD Claims

All ESRD claims with dates of service on or after July 1, 2010 must indicate on the claim if an infection was present at the time of treatment. Claims must report on each dialysis revenue code line one of the following codes:

Modifier V8: Dialysis access-related infection present (documented and treated) during the billing month. Reportable dialysis access-related infection is limited to peritonitis for peritoneal dialysis patients or bacteremia for hemodialysis patients. Facilities must report any peritonitis related to a peritoneal dialysis catheter, and any bacteremia related to hemodialysis access (including arteriovenous fistula, arteriovenous graft, or vascular catheter) if identified during the billing month. For individuals that receive different modalities of dialysis during the billing month and an infection is identified, the V8 code should only be indicated on the claim for the patient's primary dialysis modality at the time the infection was first

suspected. Non-access related infections should not be coded as V8. If no dialysis-access related infection is present during the billing month by this definition, providers should instead report modifier V9.

Modifier V9: No dialysis-access related infection, as defined for modifier V8, present during the billing month. Dialysis access-related infection, defined as peritonitis for peritoneal dialysis patients or bacteremia for hemodialysis patients must be reported using modifier V8. Providers must report any peritonitis related to a peritoneal dialysis catheter, and any bacteremia related to hemodialysis access (including arteriovenous fistula, arteriovenous graft, or vascular catheter) using modifier V8.

ESRD facilities may report the HCPCS 90999 Unlisted Dialysis Procedure Inpatient or Outpatient to report the above modifiers.

Effective April 1, 2012, the infection modifiers are terminated and reporting on the claim is no longer required.

60.1 - Lab Services

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

See the Medicare Benefit Policy Manual, Chapter 11, for a description of lab services included in the composite rate.

Independent laboratories and independent dialysis facilities with the appropriate clinical laboratory certification in accordance with CLIA may be paid for ESRD clinical laboratory tests that are separately billable. The laboratories and independent dialysis facilities are paid for separately billable clinical laboratory tests according to the Medicare laboratory fee schedule for independent laboratories. (See Chapter 16, section 40.3 for details on Part B hospital billing rules for laboratory services and Chapter 16, section 40.6 for details on ESRD billing.)

Hospital-based laboratories providing separately billable laboratory services to dialysis patients of the hospital's dialysis facility or another dialysis facility bill and are paid in accordance with the hospital outpatient laboratory provisions in Chapter 16, section 40.3. If the ESRD patient also receives other hospital outpatient services on the same day as a specimen collection and/or laboratory test, then the patient is considered to be a registered hospital outpatient and cannot be considered to be a non-patient on that day for purposes of the specimen collection and laboratory test. When the patient does not also receive hospital outpatient services on the same day as the specimen collection and/or laboratory test, then the hospital may choose to register the beneficiary as an outpatient for the specimen collection or bill for these services as non-patient on the 14x bill type.

Clinical laboratory tests are performed individually. Automated profiles and application of the "50 percent rule" can be found in Chapter 16 of this manual.

A specimen collection fee determined by CMS (as of this writing, up to $3.00) will be allowed for ESRD Method II billing only in the following circumstances:

- Drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with a syringe or vacutainer to draw the specimen).

- Collecting a urine sample by catheterization.

Laboratory tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration (as specified in the Medicare Benefit Policy Manual Pub. 100-02, Chapter 11, Section 30.2) are usually performed for dialysis patients and are routinely covered at the

frequency specified in the absence of indications to the contrary, i.e., no documentation of medical necessity is required other than knowledge of the patient's status as an ESRD beneficiary. When any of these tests is performed at a frequency greater than that specified, the additional tests are separately billable and are covered only if they are medically justified by accompanying documentation. A diagnosis of ESRD alone is not sufficient medical evidence to warrant coverage of the additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must be present on the claim. Such information must be furnished using the ICD-9-CM coding system.

Effective January 1, 2011, section 153b of the MIPPA requires that all ESRD-related lab tests must be billed by the renal dialysis facility whether provided directly or under arrangements with an independent lab. When lab services are billed by providers other than the ESRD facility and the lab furnished is designated as a lab that is included in the ESRD PPS (ESRD-related), the claim will be rejected or denied. In the event that an ESRD-related lab service was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the provider may submit a claim for separate payment using modifier AY. *ESRD facilities should only bill for labs related to the treatment of ESRD or non-ESRD related labs performed by the dialysis facility (i.e. CLIA waived lab tests). Lab tests that are not for the treatment of ESRD and not performed by the ESRD facility are not to be reported on the ESRD facility claim.*

60.3 - Blood and Blood Services Furnished in Hospital Based and Independent Dialysis Facilities

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Facility staff time used to perform any service in the dialysis unit, including time to administer blood, is included in the composite rate. However, the following may be paid in addition to the composite rate.

- Blood;
- Supplies used to administer blood; and
- Blood processing fees (e.g. blood typing and cross-matching) that are charged by the blood supplier or lb.

Hospital-based facilities - Payment is made on a reasonable cost basis in the same way as for any other Medicare beneficiary receiving blood on an outpatient basis. In determining the reasonable cost for blood, FIs consider the charges for blood from independent blood banks.

Independent dialysis facilities - Payment is made at the lower of the actual charge on the bill or a reasonable charge that the FI determines. In establishing the reasonable charge, FIs consider price lists of independent blood banks (e.g., Red Cross or hospital) that offer services to providers in the area. Also, the carrier allowable charges are considered where available.

Billing Entries related to blood - HCPCS codes and related charges are reported by both hospital-based and independent renal facilities. If HCPCS codes are sufficient to describe the services provided by blood banks in the contractors area, the carrier should establish reasonable charge amounts for the codes and make payments to facilities based on the lower of the billed charge or the reasonable charge amounts.

In some areas, blood banks group a number of services into one charge. For example, they may have one charge covering washed cells with a crossmatch. There is one HCPCS code for washed red blood cells, and there are others for typing and crossmatching. Facilities should use a combination of the available codes to reflect the one charge by the blood bank. *In general, blood processing charges are not patient-specific and are billed under revenue center 039x. Patient specific lab blood processing charges are processed as lab services under the revenue center 030x. Billing for blood, blood products and processing is further explained in publication 100-4, chapter 4.*

For supplies, facilities use revenue code 0270.

Blood and blood products remain separately payable under the ESRD PPS.

60.4 - *Erythropoietin Stimulating Agents (ESAs)*

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Coverage rules for *ESAs* are explained in the Medicare Benefit Policy Manual, Publication 100-02, chapter 11.

Fiscal intermediaries (FIs) pay for *ESAs*, to end-stage renal disease (ESRD) facilities as separately billable drug*s* to the composite rate. No additional payment is made to administer *an ESA*, whether in a facility or a home. Effective January 1, 2005, the cost of supplies to administer EPO may be billed to the FI. HCPCS A4657 and Revenue Code 270 should be used to capture the charges for syringes used in the administration of EPO.

ESAs and their administration supplies are included in the payment for the ESRD Prospective Payment System effective January 1, 2011. Providers must continue to report ESAs on the claim as ESAs are subject to a national claims monitoring program and are entitled to outlier payment consideration. The Medicare allowed payment (MAP) amount for outlier includes the ESA rate provided on the Average Sale Price (ASP) list, subject to reduction based on the ESA monitoring policy.

Medicare has an established national claims monitoring policy for erythropoietin stimulating agents for the in-facility dialysis population as outlined in the sections below.

60.4.1- ESA Claims Monitoring Policy

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Effective for services provided on or after April 1, 2006, Medicare has implemented a national claims monitoring policy for *ESAs* administered in Medicare renal dialysis facilities. This policy does not apply to claims for *ESAs* for patients who receive their dialysis at home and self-administer their *ESA*.

While Medicare is not changing its coverage policy on erythropoietin use to maintain a target hematocrit level between 30% and 36%, we believe the variability in response to *ESAs* warrants postponing requiring monitoring until the hematocrit reaches higher levels. For dates of services April 1, 2006, and later, the Centers for Medicare & Medicaid Services (CMS) *claims* monitoring *policy applies when the* hematocrit level exceeds 39.0% or the hemoglobin level exceeds 13.0g/dL. This does not preclude the contractors from performing medical review at lower levels.

Effective for services provided on or after April 1, 2006, for claims reporting hematocrit or hemoglobin levels exceeding the monitoring threshold, the dose shall be reduced by 25% over the preceding month. Providers may report that a dose reduction did occur in response to the reported elevated hematocrit or hemoglobin level by adding a GS modifier on the claim. The definition of the GS modifier *is* defined as: "Dosage of *ESA* has been reduced and maintained in response to hematocrit or hemoglobin level." Thus, for claims reporting a hematocrit level or hemoglobin level exceeding the monitoring threshold without the GS modifier, CMS will reduce the *covered* dosage reported on the claim by 25%. The excess dosage is considered to be not reasonable and necessary. Providers are reminded that the patient's medical records should reflect hematocrit/hemoglobin levels and any dosage reduction reported on the claim during the same time period for which the claim is submitted.

Effective for dates of service provided on and after January 1, 2008, requests for payments or claims for *ESAs* for ESRD patients receiving dialysis in renal dialysis facilities reporting a hematocrit level exceeding 39.0% (or hemoglobin exceeding 13.0g/dL) shall also include modifier ED **or** EE. Claims reporting neither modifier or both modifiers will be returned to the provider for correction.

The definition of modifier ED is "The hematocrit level has exceeded 39.0% (or hemoglobin 1evel has exceeded 13.0g/dL) 3 or more consecutive billing cycles immediately prior to and including the current

billing cycle." The definition of modifier EE is "The hematocrit level has exceeded 39.0% (or hemoglobin level has exceeded 13.0g/dL) less than 3 consecutive billing cycles immediately prior to and including the current billing cycle." The GS modifier continues to be defined as stated above.

Providers may continue to report the GS modifier when the reported hematocrit or hemoglobin levels exceed the monitoring threshold for less than 3 months and a dose reduction has occurred. When both modifiers GS and EE are included, no reduction in the *covered* dose will occur. Claims reporting a hematocrit or hemoglobin level exceeding the monitoring threshold and the ED modifier shall have an automatic 50% reduction in the *covered* dose applied, even if the claim also reports the GS modifier.

Below is a chart illustrating the resultant claim actions under all possible reporting scenarios:

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	**ED Modifier? (Hct >39% or Hgb >13g/dL ≥3 cycles)**	**EE Modifier? (Hct >39% or Hgb >13g/dL <3 cycles)**	**GS Modifier? (Dosage reduced and maintained)**	**Claim Action**
No	N/A	N/A	N/A	Do not reduce reported dose.
Yes	No	No	No	Return to provider for correction. Claim must report either *modifier* ED or EE.
Yes	No	No	Yes	Return to provider for correction. Claim must report either *modifier* ED or EE.
Yes	No	Yes	Yes	Do not reduce reported dose.
Yes	No	Yes	No	Reduce reported dose 25%.
Yes	Yes	No	Yes	Reduce reported dose 50%.
Yes	Yes	No	No	Reduce reported dose 50%.

In some cases, physicians may believe there is medical justification to maintain a hematocrit above 39.0% or hemoglobin above 13.0g/dL. Beneficiaries, physicians, and/or renal facilities may submit additional medical documentation to justify this belief under the routine appeal process. You may reinstate any *covered* dosage reduction amounts under this first level appeal process when you believe the documentation supports a higher hematocrit/hemoglobin level.

Providers are reminded that, in accordance with FDA labeling, CMS expects that as the hematocrit approaches 36.0% (hemoglobin 12.0g/dL), a dosage reduction occurs. Providers are expected to maintain hematocrit levels between 30.0 to 36.0% (hemoglobin 10.0-12.0g/dL). Hematocrit levels that remain below 30.0% (hemoglobin levels below 10.0g/dL)) despite dosage increases, should have causative factors

evaluated. The patient's medical record should reflect the clinical reason for dose changes and hematocrit levels outside the range of 30.0-36.0% (hemoglobin levels 10.0-12.0g/dL). Medicare contractors may review medical records to assure appropriate dose reductions are applied and maintained and hematological target ranges are maintained.

These hematocrit requirements apply only to *ESAs* furnished as an ESRD benefit under §1881(b) of the Social Security Act.

Medically Unlikely Edits (MUE)
For dates of service on and after January 1, 2008, the MUE for claims *billing* for Epogen® is reduced to 400,000 units from 500,000. The MUE for claims for Aranesp® is reduced to 1200 mcg from 1500 mcg.

For dates of service on and after April 1, 2013, the MUE for claims billing for peginesatide is applicable when units billed are equal to or greater than 26 mg.

It is likely that claims reporting doses exceeding the threshold reflect typographical errors and will be returned to providers for correction.

60.4.*2* - Facility Billing Requirements *for ESAs*
(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Hematocrit and Hemoglobin Levels
Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48.

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.

Effective January 1, 2012, ESRD facilities are required to report hematocrit or hemoglobin levels on all ESRD claims. Reporting the value 99.99 is not permitted when billing for an ESA.

The revenue codes for reporting Epoetin Alfa are 0634 and 0635. All other ESAs are reported using revenue code 0636. The HCPCS code for *the ESA* 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 units (for ESRD on Dialysis)	1/1/2007 to present
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
J0890	*Injection, Peginesatide, 0.1 mg (for ESRD on Dialysis)*	*1/1/2013 to present*

Each administration *of an ESA* 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.

Route of Administration Modifiers

Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA. Effective for claims with dates of services on or after January 1, 2012, all *facilities* billing for injections of ESA for ESRD beneficiaries must include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. ESRD claims containing ESA administrations that are submitted without the route of administration modifiers will be returned to the provider for correction. Renal dialysis facilities claim including charges for administrations of the ESA by both methods must report separate lines to identify the number of administration provided using each method

ESA Monitoring Policy Modifiers

Append modifiers ED, EE and GS as applicable, see instructions in section 60.4.1.

Maximum Allowable Administrations

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

The maximum number of administrations of Aranesp for a billing cycle is 5 times in 30/ 31days.

The maximum number of administrations of Peginesatide for a billing cycle is 1 time in 30/ 31days.

60.4.*3* Epoetin Alfa (EPO) Supplier Billing Requirements (Method II) on the Form CMS-1500

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Note: Effective January 1, 2011 Method II and Supplier billing for ESRD related items and services is no longer applicable. The Medicare Improvements for Patients and Providers Act (MIPPA) section 153b requires that all payments related to the treatment of ESRD be paid to the ESRD facility treating the patient.

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 X 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 *through December 31, 2010*.

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:

The 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.*3.1* - Other Information Required on the Form CMS-1500 for Epoetin Alfa (EPO)

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Note: Effective January 1, 2011 Method II and Supplier billing for ESRD related items and services is no longer applicable. The Medicare Improvements for Patients and Providers Act (MIPPA) section 153b requires that all payments related to the treatment of ESRD be paid to the ESRD facility treating the patient.

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.*3.2*- Completion of Subsequent Form CMS-1500 Claims for Epoetin Alfa (EPO)
(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Subsequent claims are completed as initial claims in §60.4.*2.3*, 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.

Number of Units Administered - Subsequent claims may be submitted electronically.

60.4.*4* - Payment Amount for Epoetin Alfa (EPO)
(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Payment for ESRD-related EPO is included in the ESRD PPS for claims with dates of service on or after January 1, 2011.

Dates of service prior to January 1, 2005, the *Medicare contractor* 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 *Medicare contractor*. 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:

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 x $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 x $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 morrow 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 morrow 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.

Payment for ESRD-related EPO is included in the ESRD PPS for claims with dates of service on or after January 1, 2011.

60.4.*4.1* - Payment for Epoetin Alfa (EPO) in Other Settings

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

With the implementation of the ESRD PPS, ESRD-related EPO is included in ESRD PPS payment amount and is not separately payable on Part B claims with dates of service on or after January 1, 2011 for other providers with the exception of a hospital billing for an emergency or unscheduled dialysis session.

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

In the hospital inpatient setting, payment under Part B is made on bill type 12x. Hospitals report the drug units based on the units defined in the HCPCS description. Hospitals do not report value code 68 for units of EPO. For dates of service prior to April 1, 2006, report EPO under revenue code 0636. For dates of service from April 1, 2006 report EPO under the respective revenue code 0634 for EPO less than 10,000 units and revenue code 0635 for EPO over 10,000 units. Payment will be based on the ASP Pricing File.

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.

60.4.4.2 - Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

When ESRD patients come to the hospital for an unscheduled or emergency dialysis treatment they may also require the administration of EPO. Effective January 1, 2005, EPO will be paid based on the ASP Pricing File.

Hospitals use type of bill 13X (or 85X for Critical Access Hospitals) and report charges under the respective revenue code 0634 for EPO less than 10,000 units and revenue code 0635 for EPO over 10,000 units. Hospitals report the drug units based on the units defined in the HCPCS description. Hospitals do not report value code 68 for units of EPO. Value code 49 must be reported with the hematocrit value for the hospital outpatient visits prior to January 1, 2006, and for all claims with dates of service on or after January 1, 2008.

60.4.5 - ESAs Furnished to Home Patients

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Payment for ESRD-related ESA is included in the ESRD PPS for claims with dates of service on or after January 1, 2011.

Medicare covers ESAs for dialysis patients who use ESAs 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 an ESA 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 an ESA 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 an ESA 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 an ESA furnished by a physician to a patient for self-administration.

The DMERCs pay for EPO for Method II ESRD beneficiaries only. DMERCs shall deny claims for EPO where the beneficiary is not a Method II home dialysis patient.

When denying line items for patients that are not Method II, use the following message on the remittance advice:

The ANSI message 7011: Claim not covered by this payer contractor. You must send the claim to the correct payer contractor.

When denying line items for patients that are not Method II, use the following message on the Medicare Summary Notice (MSN):

English: 8.59- Durable Medical Equipment Regional Carriers pay for Epoetin Alfa and Darbepoetin Alfa only for Method II End Stage Renal Disease home dialysis patients.

Spanish: 8.59- Las Empresas Regionales de Equipo Médico Duradero pagan por los medicamentos Epoetina Alfa y Darbepoetina Alfa sólo a pacientes del Método II de diálisis con enfermedad renal en etapa final que están confinados al hogar.

60.4.5.1 - Self Administered ESA Supply

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Initially, facilities may bill for up to a 2-month supply of an ESA 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 an ESA furnished a beneficiary. Usually, revenue code 0635 would apply to EPO 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 claims with dates of service on or after January 1, 2008, supplies of an ESA 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 an ESA 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)".

When billing for drug wastage in accordance with the policy in chapter 17 of this manual, section 40.1 the provider must show the wastage on a separate line item with the modifier JW. The line item date of service should be the date of the last covered administration according to the plan of care or if the patient dies use the date of death.

Condition code 70 should be reported on claims billing for home dialysis patients that self administer anemia management drugs including ESAs.

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

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Note: Effective January 1, 2011 Method II and Supplier billing for ESRD related items and services is no longer applicable. The Medicare Improvements for Patients and Providers Act (MIPPA) section 153b requires that all payments related to the treatment of ESRD be paid to the ESRD facility treating the patient.

The 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 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. 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.

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

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

Note: Effective January 1, 2011 Method II and Supplier billing for ESRD related items and services is no longer applicable. The Medicare Improvements for Patients and Providers Act (MIPPA) section 153b requires that all payments related to the treatment of ESRD be paid to the ESRD facility treating the patient.

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

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

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

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.*

60.4.6.3 - Payment Amount for Darbepoetin Alfa (Aranesp)

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

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. Effective January 1, 2005, Aranesp will be paid based on the ASP Pricing File. 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.

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.

Payment for ESRD-related Aranesp is included in the ESRD PPS for claims with dates of service on or after January 1, 2011.

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

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

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

In the hospital inpatient setting, payment under Part B is made on bill type 12x when billed with revenue code 0636. The total number of units as a multiple of 1mcg is placed in the unit field. Reimbursement is based on the payment allowance limit for Medicare Part B drugs as found in the ASP pricing file.

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.

With the implementation of the ESRD PPS, ESRD-related Aranesp is included in the ESRD PPS payment amount and is not separately payable on Part B claims with dates of service on or after January 1,2011 for other providers, with the exception of a hospital billing for an emergency or unscheduled dialysis session.

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

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

When ESRD patients come to the hospital for an unscheduled or emergency dialysis treatment they may also require the administration of Aranesp. For patients with ESRD who are on a regular course of dialysis, Aranesp administered in a hospital outpatient department is paid the MMA Drug Pricing File rate. Effective January 1, 2005, Aranesp will be paid based on the ASP Pricing File.

Hospitals use bill type 13X (or 85X for Critical Access Hospitals) and report charges under revenue code 0636. The total number of units as a multiple of 1mcg is placed in the unit field. Value code 49 must be reported with the hematocrit value for the hospital outpatient visits prior to January 1, 2006, and for all claims with dates of service on or after January 1, 2008.

60.4.7 Payment for Peginesatide in the Hospital Outpatient Department

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)

When ESRD patients come to the hospital for an unscheduled or emergency dialysis treatment they may also require the administration of an ESA, such as peginesatide. When hospitals bill for an unscheduled or emergency outpatient dialysis session (G0257) they may include the administration of an ESA.

60.7– Reserved

(Rev.2582, Issued: 11-02-12, Effective: 04-01-13, Implementation: 04-01-13)