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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 2361 | Date: November 25, 2011 |
| | Change Request 7593 |

Transmittal 2335, dated October 28, 2011 is being rescinded and replaced by Transmittal 2361, dated November 25, 2011 to correct the description of the Kt/V reporting in publication 100-4, chapter 8 Section 50.9 to conform to the instructions in CR 7460.

SUBJECT: Clarification and Revisions for Claims Submitted for End Stage Renal Disease (ESRD) Patients

I. SUMMARY OF CHANGES: This instruction includes several revisions and clarifications regarding the instructions published for the ESRD Prospective Payment System and the ESRD Quality Incentive Program. Including the onset of dialysis adjustment, payment for the drug Vancomycin, laboratory services during an emergency room service, reporting of the Kt/V value, and reporting hematocrit and hemoglobin readings for all ESRD patients.

EFFECTIVE DATE: January 1, 2012 and April 1, 2012 as indicated in Section I. B. Policy
IMPLEMENTATION DATE: April 2, 2012

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 | 4 / 180.6/Emergency Room (ER) Services That Span Multiple Service Dates |
| R | 8 / 20.1/Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate |
| R | 8 / 50.1.6/Laboratory Services Performed During Emergency Room Service |
| R | 8 / 50.9/Coding for Adequacy of Dialysis, Vascular Access and Infection |
| R | 8 / 60.2.1.1/Separately Billable ESRD Drugs |
| R | 8 / 60.4/Epoetin Alfa (EPO) |
| R | 8 / 60.7/Darbepoetin Alfa (Aranesp) for ESRD Patients |

III. FUNDING:

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

No additional funding will be provided by CMS; Contractor activities are to be carried out within 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 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.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment – Business Requirements

| | | | |
|-------------|-------------------|-------------------------|----------------------|
| Pub. 100-04 | Transmittal: 2361 | Date: November 25, 2011 | Change Request: 7593 |
|-------------|-------------------|-------------------------|----------------------|

Transmittal 2335, dated October 28, 2011 is being rescinded and replaced by Transmittal 2361, dated November 25, 2011 to correct the description of the Kt/V reporting in publication 100-4, chapter 8 Section 50.9 to conform to the instructions in CR 7460.

SUBJECT: Clarification and Revisions for Claims Submitted for End Stage Renal Disease (ESRD) Patients

Effective Date: January 1, 2012 and April 1, 2012 as indicated in Section I.B. Policy

Implementation Date: April 2, 2012

I. GENERAL INFORMATION

A. Background: This instruction includes several revisions and clarifications regarding the instructions published for the ESRD Prospective Payment System and the ESRD Quality Incentive Program.

Clarification of the Onset of Dialysis Adjustment for ESRD Claims

The 2011 final rule for the End Stage Renal Disease Prospective Payment System (PPS), published on August 12, 2010 implemented a case-mix adjusted bundled PPS effective January 1, 2011. In this rule, CMS finalized a payment adjustment for dialysis treatments furnished to adults for onset of dialysis. This adjustment is applied to each dialysis treatment that is furnished to adult patients who are eligible to receive Medicare coverage during their first 120 calendar days of dialysis. This adjustment is determined by the dialysis start date in the Common Working File as provided on the CMS Form 2728 completed by the provider and certified by the practitioner.

Subsequent to the publication of the ESRD PPS final rule, there has been confusion as to how often the onset of dialysis adjustment can apply. The onset of dialysis is a one-time adjustment. That is, payment for the onset of dialysis is only provided during the initial 120 calendar days from when an ESRD beneficiary began their maintenance dialysis. The onset of dialysis adjustment does not restart and apply when a patient receives dialysis at a different facility or when dialysis resumes after a failed kidney transplant.

Revision to ESRD Claims Reporting Vancomycin

Change Request (CR) 7064, Transmittal 2134, entitled “End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services” implemented the ESRD PPS. CR 7064 provided ESRD consolidated billing requirements for certain Part B services included in the ESRD facility bundled payment. All drugs reported on the ESRD facility claim that do not have an AY modifier are considered included in the ESRD PPS. The list of drugs and biologicals for consolidated billing are designated as always ESRD-related and therefore separate payment is not made to ESRD facilities. However, subsequent to the publication of the CY 2011 ESRD PPS final rule and CR 7064, CMS received numerous comments indicating that Vancomycin is indicated for both ESRD and non-ESRD conditions. After consultation with CMS Medical Advisors, CMS concur with this assessment.

Revision to Hospitals Reporting Emergency Related Laboratory Services

CR 7471, Transmittal 2266, entitled “Implementation of Changes to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Outlier Payment Policy and Changes to the ESRD PPS Consolidated Billing Requirements for Laboratory Services Furnished in a Hospital Emergency Room or Department” implemented

a bypass of the ESRD PPS consolidated billing requirements for ESRD-related laboratory services furnished to ESRD patients in an emergency room or emergency department on the same date of service as the emergency visit. Subsequent to the issuance of CR 7471, CMS found that there are situations where an ESRD-related laboratory service may be furnished to an ESRD patient in an emergency room or emergency department on a different date of service. For example, the patient may have gone to the emergency room at 10:30pm one evening but did not receive laboratory testing until 1am the next day. This instruction will allow for identifying and reporting of emergency related laboratory services not performed on the same date of service as the emergency visit.

Clarification of ESRD Claims Reporting the Kt/V Value

CR 7460, Transmittal 2262, entitled “ Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims” provided instructions for calculating the Kt/V value for reporting on the claim. When reporting a value of 8.88 the date of a Kt/V reading is not required, however the standard system will require a date until April 1, 2012. Facilities that do not have a date to report may use any date within the billing period until April when the date will no longer be required.

Revision to ESRD Claim Requirements for Reporting a Hematocrit or Hemoglobin

CR 7460, Transmittal 2262, entitled “ Implementation of the MIPPA 153c End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) and Other Requirements for ESRD Claims” provided requirements for ESRD facilities to report a hematocrit or hemoglobin reading all ESRD claims. However, transmittal 2262 did not provide instructions in the event a facility does not have a hematocrit or hemoglobin reading to report. As a result, this instruction will require that a facility that does not have a hematocrit or hemoglobin to report must submit a default value of 99.99 to indicate no reading was available. In compliance with the CMS long-standing policy that requires that a hematocrit or hemoglobin be reported when an Erythropoiesis Stimulating Agent (ESA) is administered, the value 99.99 may not be used.

B. Policy:

Clarification of the Onset of Dialysis Adjustment for ESRD Claims, Effective April 1, 2012

No change in policy. System changes will be implemented to support the existing policy.

Revision to ESRD Claims Reporting Vancomycin, Effective January 1, 2012

ESRD facilities have the ability to receive separate payment for Vancomycin furnished on or after January 1, 2012, by placing the AY modifier on the claim when Vancomycin is furnished to treat non-ESRD related conditions. The ESRD facility is required to indicate (in accordance with ICD-9 guidelines) the diagnosis code for which the Vancomycin is indicated. CMS contractors are advised to reprocess ESRD claims with dates of service from January 1, 2012 through March 31, 2012 containing Vancomycin with the AY modifier.

Hospitals Reporting Emergency Related Laboratory Services, Effective April 1, 2012

CMS is requiring that hospitals append an ET modifier to ESRD-related laboratory tests furnished to ESRD patients on a day other than the date of the emergency room or emergency department visit to indicate that the laboratory test was furnished in conjunction with the emergency visit. Appending the ET modifier indicates that the laboratory service being furnished on a day other than the emergency visit is related to the emergency visit and therefore at the time the laboratory test was ordered, the ordering physician was unable to determine if it is being ordered for reasons of treating the patient’s ESRD.

Clarification of ESRD Claims Reporting the Kt/V Value, Effective January 1, 2012

When reporting a value of 8.88 the date of a Kt/V reading is not required. System changes will be implemented to no longer require a date be reported when the value being reported is 8.88.

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|--|---|---|--------------------------------|---------------------------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B M A C | D M E M A C | F I M A C | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | | | | | | F I S S | M C S | V M S | C W F | |
| | 1, 2012, Medicare contractors shall amend the ESRD laboratory consolidated billing edit bypass for ER services established with CR 7471, to require a modifier ET on the hospital lab service line item when the line item date of service differs from the revenue code 45x line item date of service. | | | | | | | | | | |
| 7593.4.1 | Medicare contractors shall reject hospital outpatient laboratory services subject to the ESRD lab CB edit when the ER revenue code 45x is not the same line item date of service and the ET modifier is not present on the lab line item. | | | | | | X | | | X | |
| Revision to ESRD Claim Requirements for Reporting a Hematocrit or Hemoglobin, Effective April 1, 2012 | | | | | | | | | | | |
| 7593.5 | Medicare contractors shall return to the provider all 72x type of bills with dates of service on or after April 1, 2012 that do not contain a value code 48 or 49. | X | | X | | | X | | | | |
| 7593.5.1 | Medicare contractors shall accept a value of 99.99 in the value code 48 or value code 49 field, unless the claim is billing for an ESA (Q4081, J0882) | X | | X | | | X | | | | |
| 7593.5.2 | Medicare contractors shall return to the provider 72x type of bills reporting an ESA (Q4081 or J0882) and reporting a value of 99.99 in value code 48 or 49. | X | | X | | | X | | | | |

III. PROVIDER EDUCATION TABLE:

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|--------|---|---|--------------------------------|---------------------------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A / B M A C | D M E M A C | F I M A C | C A R R I E R | R H H I | Shared-System Maintainers | | | | OTHER |
| | | | | | | | F I S S | M C S | V M S | C W F | |
| 7593.6 | 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 site and include information about it | X | | X | | | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|--------|---|---|-------------|--------|---------------------------------|-------------|------------------------------|-------------|-------------|-------------|-------|
| | | A / B | D M E | F I | C A R R I E R | R H I | Shared-System Maintainers | | | | OTHER |
| | | M A C | M A C | | | | F I S S | M C S | V M S | C W F | |
| | in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | | | | | | | | | | |

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
| | |

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Claims Processing Wendy.Tucker@cms.hhs.gov 410-786-3004, Payment Policy Michelle.Cruse@cms.hhs.gov 410-786-7540, Quality Reporting Thomas.Dudley@cms.hhs.gov 410-786-1442.

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

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*:

No additional funding will be provided by CMS; contractor activities are to be carried out within 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 does 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.

180.6 – Emergency Room (ER) Services That Span Multiple Service Dates
(Rev. 2361, Issued: 11-25-11, Effective: 01-01-12 and 04-01-12, Implementation; 04-02-12)

Emergency room (ER) services provided by hospital outpatient departments (OPPS & Non-OPPS) should be billed in the following manner:

- Emergency room services are reported under the 045x revenue code
- The line item date of service for the ER encounter is the date the patient entered the ER even if the patients encounter spans multiple service dates
- For all other services related to the ER encounter (i.e., lab, radiology, etc) the line item date of service reported is the date the service was actually rendered

Note: For patients in a Skilled Nursing Facility (SNF) see Chapter 6, Section 20.1.2.2 “Emergency Services” for special billing instructions using the ET modifier. *Chapter 6, Section 20.1.2.2* applies to hospital ER services spanning multiple service dates that are provided to patients in a Part A SNF stay and related CWF SNF consolidated billing edits.

For patients with end stage renal disease (ESRD) see Chapter 8, Section 50.1.6 for billing instructions requiring the use of the ET modifier. Chapter 8, Section 50.1.6 applies to hospital ER services spanning multiple service dates including laboratory services.

20.1 – Calculation of the Basic Case-Mix Adjusted Composite Rate and the ESRD Prospective Payment System Rate

(Rev. 2361, Issued: 11-25-11, Effective: 01-01-12 and 04-01-12, Implementation; 04-02-12)

A case mix methodology adjusts the composite payment rate based on a limited number of patient characteristics. Variables for which adjustments will be applied to each facility’s composite rate include age, body surface area (BSA), and low body mass index (BMI). These variables are determined in the ESRD PRICER to calculate the final composite rate (including all other adjustments).

The following table contains claim data required to calculate a final ESRD composite rate and the ESRD PPS rate:

| UB-04 Claim Items | ASC X12N 837i |
|--|------------------------------------|
| Through Date | 2300 DTP segment 434 qualifier |
| Date of Birth | 2010BA DMG02 |
| Condition Code (73 or 74) | 2300 HI segment BG qualifier |
| Value Codes (A8 and A9) / Amounts | 2300 HI segment BE qualifier |
| Revenue Code (0821, 0831, 0841, 0851, 0880, or 0881) | 2400 SV201 |

For claims with dates of service on or after January 1, 2011, Medicare systems must pass the line item date of service dialysis revenue code lines when the onset of dialysis adjustment is applicable to one or more of the dialysis sessions reported on the claim.

| | |
|---|-----------------------------------|
| Line Item Date of Service for Revenue Code (0821, 0831, 0841, 0851) | 2400 DTP Segment D8 qualifier |
|---|-----------------------------------|

In addition to the above claim data, the following payer only codes are required on claims with dates of service on or after January 1, 2011 to calculate the final ESRD PPS rate:

| | |
|---|----------------------------------|
| Payer Only Condition Codes (MA, MB, MC, MD, ME, MF) | 2300 HI segment BG qualifier |
| Payer Only Value Code (79) | 2300 HI segment BE qualifier |

Note: These payer only codes above are assigned by the Medicare standard systems and are not submitted on the claim by the provider. Payer only condition codes are only applicable when the appropriate corresponding diagnosis code(s) appears on the claim.

See information below in this section on co-morbidly diagnostic categories. The payer only value code 79 represents the dollar amount for services applicable for the calculation in determining an outlier payment.

The following provider data must also be passed to the ESRD PRICER to make provider-specific calculations that determine the final ESRD rate:

| Field | Format |
|---------------------------------|---------------|
| Actual Geographic Location MSA | X(4) |
| Actual Geographic Location CBSA | X(5) |
| Special Wage Index | 9(2)V9(4) |
| Provider Type | X(2) |
| Special Payment Indicator | X(1) |

In addition to the above provider data, the following is required to calculate the final ESRD PPS rate effective January 1, 2011:

| | |
|---------------------------|-------|
| Blended Payment Indicator | X(1) |
| Low-Volume Indicator | X (1) |

Effective January 1, 2012 the following is required to calculate the Quality Incentive Program adjustment for ESRD facilities:

| | |
|-------------------------|------|
| Quality Indicator Field | X(1) |
|-------------------------|------|

ESRD facilities may elect to be reimbursed 100 percent by ESRD PPS no later than November 1, 2010. Facilities that do not elect to be reimbursed 100 percent by the ESRD PPS will be reimbursed by a blended payment rate which is composed of the current basic case-mix adjusted composite rate payment system and the new ESRD PPS.

Blended payment schedule:

Calendar year 2011 – 75 percent of the old payment methodology and 25 percent of new ESRD PPS payment

Calendar year 2012 – 50 percent of the old payment methodology and 50 percent of the new ESRD PPS payment

Calendar year 2013 – 25 percent of the old payment methodology and 75 percent of the new ESRD PPS payment

Calendar year 2014 – 100 percent of the ESRD PPS payment

Based on the claim and provider data shown above, the ESRD PRICER makes adjustments to the facility specific base rate to determine the final composite payment rate. The following factors are used to adjust and make calculations to the final payment rate:

| | | |
|---------------|--|--|
| Provider Type | Drug add-on | Budget Neutrality Factor |
| Patient Age | Patient Height | Patient Weight |
| Patient BSA | Patient BMI | BSA factor |
| BMI factor | Condition Code 73 adjustment (if applicable) | Condition Code 74 adjustment (if applicable) |

In addition to the above adjustments, the following adjustments may be applicable to the ESRD PPS base rate for **adult** patient claims with dates of service on or after January 1, 2011:

| | | |
|-------------------|------------------------|--------------------------|
| Onset of Dialysis | Patient Co-morbidities | Low-Volume ESRD Facility |
|-------------------|------------------------|--------------------------|

Onset of Dialysis:

Providers will receive an adjustment to the ESRD PPS base rate for patients within the *initial 120 calendar days from when an ESRD beneficiary began their maintenance dialysis*. The provider does not report anything on the claim for this adjustment. The adjustment is determined by the start date of dialysis in the Common Working File as reported on the patient's 2728 form. When the onset of dialysis adjustment is provided, the claim is not entitled to a co-morbidity adjustment or a training add-on adjustment.

Co-morbidity Adjustment Categories

The ESRD PPS will provide adjustments for 6 categories of co-morbidity conditions. Three categories of chronic conditions and 3 categories of acute conditions. **In the event that more than one of the co-morbidity categories is present on the claim, the claim will be adjusted for the highest paying co-morbidity category.**

Acute Co-morbidity Diagnostic Categories:

The acute co-morbidity categories will be eligible for a payment for the first month reported and the following 3 consecutive months. Acute co-morbidity conditions reported for more than 4 consecutive months will not receive additional payment. In the event that the co-morbidity condition was resolved and later reoccurred, the provider may submit a condition code to indicate the diagnosis is a reoccurrence. The adjustment will be applicable for an additional 4 months.

Acute Categories are:

- Gastro-intestinal tract bleeding
- Bacterial pneumonia
- Pericarditis

Chronic Co-morbidity Diagnostic Categories:

When chronic co-morbidity codes are reported on the claim an adjustment may be made for as long as the chronic condition remains applicable to the patient care provided and is reported on the claim.

Chronic Categories are:

- Hereditary hemolytic or sickle cell anemia
- Monoclonal gammopathy
- Myelodysplastic syndrome

Information related to the comorbid conditions eligible for adjustment can be found at the **following website:**

http://www.cms.gov/ESRDPayment/40_Comorbid_Conditions.asp#TopOfPage. . This list may be updated as often as quarterly in January, April, July and October of each year.

Low-Volume Facilities:

ESRD facilities will receive an adjustment to their ESRD PPS base rate when the facility furnished less than 4,000 treatments in each of the three cost report years preceding the payment year and has not open, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year. The ESRD facility must notify their Medicare Contractor if they believe they are eligible for the low-volume adjustment. Contractors must validate the eligibility and update the provider specific file. Pediatric patient claims are not eligible for the low-volume adjustment.

Medicare contractors are instructed to validate the facility's eligibility for the low volume adjustment. If a Medicare contractor determines that an ESRD facility has received the low volume adjustment in error, the contractor is required to adjust all of the ESRD facility's affected claims to remove the adjustment within 6 months of finding the error.

In addition to the above adjustments, the following adjustments may be applicable to the ESRD PPS base rate for **adult and pediatric** patient claims with dates of service on or after January 1, 2011:

Training Adjustment: The ESRD PPS provides a training add-on of \$33.44 adjusted by the geographic area wage index that accounts for an hour of nursing time for training treatments. The add-on applies to both PD and HD training treatments.

ESRD PPS Outlier Payments:

Outlier payments may be applied to the payment. ESRD outlier services are the following items and services that are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011 separately billable under Part B; (3) medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis service drugs that were or would have been, prior to January 1, 2011 covered under Medicare Part D. ESRD-related oral only drugs are delayed until January 1, 2014. Services not included in the PPS that remain separately payable are not considered outlier services.

When the ESRD PRICER returns an outlier payment, the standard systems shall display the total applicable outlier payment on the claim with value code 17.

Information related to the outlier services eligible for adjustment can be found at the following website: http://www.cms.gov/ESRDPayment/30_Outlier_Services.asp#TopOfPage. This list may be updated as often as quarterly in January, April, July and October of each year.

For claims submitted with dates of service on or after January 1, 2012, all drugs reported on the ESRD claim under revenue codes 0634, 0635 and 0636 with a rate available on the ASP file will be considered in the Medicare allowed payment (MAP) amount for outlier consideration with the exception of any drugs reported with the AY modifier and drugs included in the original composite rate payment system.

Value Codes and Amounts

48 - Hemoglobin Reading - Code indicates the *most recent* hemoglobin reading taken before the *start of* this billing *period*. This is usually reported in three positions with a decimal. Use the right of the delimiter for the third digit.

The blood sample for the hemoglobin reading must be obtained before the dialysis treatment. If a hemoglobin value is not available facilities must report the value 99.99.

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

The blood sample for the hematocrit reading must be obtained before the dialysis treatment. If a hematocrit value is not available facilities must report the value 99.99.

50.1.6 - Laboratory Services Performed During Emergency Room Service *(Rev. 2361, Issued: 11-25-11, Effective: 01-01-12 and 04-01-12, Implementation; 04-02-12)*

For claims with dates of service on or after January 1, 2012, the consolidated billing edit for laboratory services will be bypassed when billed in conjunction with an emergency room service on a hospital outpatient claim and the AY modifier will not be necessary. Allowing laboratory testing to bypass consolidated billing edits in the emergency room or department does not mean that ESRD facilities should send patients to the emergency room or department for routine laboratory testing or for the provision of renal dialysis services that should be provided by ESRD facilities. The intent of the bypass is to acknowledge that there are emergency circumstances where the reason for the patient's illness is unknown and the determination of a laboratory test as being ESRD-related is not known.

For hospital claims with dates of service on or after April 1, 2012, that include an emergency room service with revenue code 045x on a line item date that differs from the line item date of service for the related laboratory test(s) the hospital must include the modifier ET to attest that the laboratory test(s) were ordered in conjunction with the emergency services. This is necessary to recognize that emergency services often span two calendar days.

50.9 - Coding for Adequacy of Dialysis, Vascular Access and Infection *(Rev. 2361, Issued: 11-25-11, Effective: 01-01-12 and 04-01-12, Implementation; 04-02-12)*

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.

60.2.1.1 – Separately Billable ESRD Drugs

(Rev. 2361, Issued: 11-25-11, Effective: 01-01-12 and 04-01-12, Implementation; 04-02-12)

The following categories of drugs (including but not limited to) are separately billable when used to treat the patient's renal condition:

- Antibiotics;
- Analgesics;
- Anabolics;
- Hematinics;
- Muscle relaxants;
- Sedatives;
- Tranquilizers; and
- Thrombolytics: used to declot central venous catheters.

NOTE: Erythropoietin replacement therapies are separately billable and paid at established rates through appropriate billing methodology: Eprex (EPO) §60.4 and Darbepoetin Alfa (Aranesp) §60.7.

These separately billable drugs may only be billed by an ESRD facility if they are actually administered in the facility by the facility staff. Staff time used to administer separately billable drugs is covered under the composite rate and may not be billed separately. However, the supplies used to administer these drugs may be billed in addition to the composite rate.

Effective January 1, 2011, section 153b of the MIPPA requires that all ESRD-related drugs and biologicals be billed by the renal dialysis facility. When a drug or biological is billed by providers other than the ESRD facility and the drug or biological furnished is designated as a

drug or biological that is included in the ESRD PPS (ESRD-related), the claim will be rejected or denied. In the event that an ESRD-related drug or biological 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.

All drugs reported on the renal dialysis facility claim are considered included in the ESRD PPS. The list of drugs and biologicals for consolidated billing are designated as always ESRD-related and therefore not allowing separate payment to be made to ESRD facilities.

Effective January 1, 2012, Vancomycin is the exception to this policy. Because Vancomycin may be indicated for both ESRD and non-ESRD conditions, ESRD facilities have the ability to receive separate payment for Vancomycin by placing the AY modifier on the claim when Vancomycin is furnished to treat non-ESRD related conditions. The ESRD facility is required to indicate (in accordance with ICD-9 guidelines) the diagnosis code for which the Vancomycin is indicated. Items and services subject to the consolidated billing requirements for the ESRD PPS can be found on the CMS website at:
http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage.

Other drugs and biologicals may be considered separately payable to the dialysis facility if the drug was not for the treatment of ESRD. The facility must include the modifier AY to indicate it was not for the treatment of ESRD.

Drugs are assigned HCPCS codes. If no HCPCS code is listed for a drug (e.g., a new drug) the facility bills using HCPCS code J3490, "Unclassified Drugs," and submits documentation identifying the drug. To establish a code for the drug, the FI checks HCPCS to verify that there is no acceptable HCPCS code for billing and if a code is not found checks with the local carrier, which may have a code and price that is appropriate. If no code is found the drug is processed under HCPCS code J3490. See Chapter 17 for a complete description of drug pricing.

60.4 - Epoetin Alfa (EPO)

(Rev. 2361, Issued: 11-25-11, Effective: 01-01-12 and 04-01-12, Implementation; 04-02-12)

Coverage rules for Epoetin Alfa (EPO) are explained in the Medicare Benefit Policy Manual, Publication 100-02, chapter 11. For an explanation of Method I and Method II reimbursement for patients dialyzing at home, see §40.1.

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

If the beneficiary obtains EPO from a supplier for self-administration, the supplier bills the durable medical equipment regional carrier (DMERC) and the DMERC pays at the rate shown in §60.4.3

Program payment may not be made to a physician for EPO for self-administration. Where EPO is furnished by a physician payable as “incident to services” the carrier processes the claim.

EPO Payment Methodology

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

Medicare pays for a drug if self-administered by a dialysis patient. When EPO is administered in a renal facility, the service is not an “incident to” service and not under the “incident to” provision.

Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48. See §60.4.1.

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

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

While Medicare is not changing its coverage policy on erythropoietin use to maintain a target hematocrit level between 30% and 36%, we believe the variability in response to EPO warrants postponing requiring monitoring until the hematocrit reaches higher levels. For dates of services April 1, 2006, and later, the Centers for Medicare & Medicaid Services (CMS) will not initiate monitoring until 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. The Food and Drug Administration (FDA) labeling for EPO notes that as the hematocrit approaches a reading of 36.0 (or hemoglobin 12.0g/dL), the dose of the drug should be reduced by 25%.

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 continues to be defined as: “Dosage of EPO or Darbepoetin Alfa 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 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 EPO 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 level 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 reported 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 reported 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 ED or EE. |
| Yes | No | No | Yes | Return to provider for correction. Claim must report either 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 addition, for dates of service on and after January 1, 2008, CMS will implement a revised medically unbelievable edit (MUE). For dates of service on and after January 1, 2008, the MUE for claims for Epogen® is reduced to 400,000 units from 500,000. It is likely that claims reporting doses exceeding the new threshold reflect typographical errors and will be returned to providers for correction.

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 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 EPO furnished as an ESRD benefit under §1881(b) of the Social Security Act. EPO furnished incident to a physician's service is not included in this policy. Carriers have discretion for local policy for EPO furnished as "incident to service."

60.7 – Darbepoetin Alfa (Aranesp) for ESRD Patients

(Rev. 2361, Issued: 11-25-11, Effective: 01-01-12 and 04-01-12, Implementation; 04-02-12)

Coverage rules for Aranesp® are explained in the Medicare Benefit Policy Manual, Publication 100-02, chapter 11. For an explanation of Method I and Method II reimbursement for patients dialyzing at home see §40.1.

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

If the beneficiary obtains Aranesp® from a supplier for self-administration, the supplier bills the durable medical equipment regional carrier (DMERC), and the DMERC pays in accordance with MMA Drug Payment Limits Pricing File.

Program payment may not be made to a physician for self-administration of Aranesp®. When Aranesp® is furnished by a physician as “incident to services,” the carrier processes the claim.

For ESRD patients on maintenance dialysis treated in a physician’s office, code J0882, “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 J0882.

Darbepoetin Alfa Payment Methodology

| Type of Provider | Separately Billable | DMERC Payment | No Payment |
|--|---------------------|---------------|------------|
| In-facility freestanding and Hospital-based ESRD facility | X | | |
| Self-administer Home Method I | X | | |
| Self-administer Home Method II | | X | |
| Incident to physician in facility or for self-administration * | | | X |

Medicare pays for a drug if self-administered by a dialysis patient. When Aranesp® is administered in a dialysis facility, the service is not an “incident to” service, and not under the “incident to” provision.

Renal dialysis facilities are required to report hematocrit or hemoglobin levels for their Medicare patients receiving erythropoietin products. Hematocrit levels are reported in value code 49 and reflect the most recent reading taken before the start of the billing period. Hemoglobin readings before the start of the billing period are reported in value code 48. See §60.4.1.

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

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

While Medicare is not changing its coverage policy on erythropoietin use to maintain a target hematocrit level between 30% and 36%, we believe the variability in response to EPO warrants postponing requiring monitoring until the hematocrit reaches higher levels. For dates of services on and after April 1, 2006, the Centers for Medicare & Medicaid Services (CMS) will not initiate monitoring until 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. The Food and Drug Administration (FDA) labeling for Aranesp® notes that as the hematocrit approaches a reading of 36.0% (or hemoglobin 12.0g/dL), the dose of the drug should be reduced by 25%.

Effective for dates of service 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 continues to be defined as: “Dosage of EPO or Darbepoetin Alfa 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 shall reduce the 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 an after January 1, 2008, requests for payments or claims for Aranesp® 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 level 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 reported 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 reported 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 ED or EE. |
| Yes | No | No | Yes | Return to provider for correction. Claim must report either 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 addition, for dates of service on and after January 1, 2008, CMS will implement a revised medically unbelievable edit (MUE). For dates of service on and after January 1, 2008, the MUE for claims for Aranesp® is reduced to 1200 mcg from 1500 mcg. It is likely that claims reporting doses exceeding the new threshold reflect typographical errors and will be returned to providers for correction.

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 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 Aranesp® furnished as an ESRD benefit under §1881(b) of the Social Security Act. Aranesp® furnished incident to a physician's service is not included in this policy. Carriers have discretion for local policy for Aranesp® furnished as "incident to service."