

Coding

Guidelines

Contractor Name

Wisconsin Physicians Service (WPS)

Contractor Number

00951, 00952, 00953, 00954
05101, 05201, 05301, 05401,
05102, 05202, 05302, 05402,
52280

LCD Title

Erythropoiesis Stimulating Proteins
Epoetin alfa (EPO), Darbepoetin alfa (DPA)

LCD Database ID Number

Contractor's Determination Number

INJ-023

CMS National Coverage Policy

Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Social Security Act (the Act) §1881(b) **Renal Dialysis Facilities**

Medicare Benefit Policy Manual, Chapter 11, section 90

Medicare Benefit Policy Manual, Chapter 15, section 50.5.2, Erythropoietin (EPO) which discusses ESAs for end-stage renal disease related anemia.

Medicare Claims Processing Manual, Chapter 8, Sections 60.7 and 60.4)

Medicare Claims Processing Manual, Transmittal No. 1212, Change Request #5480, March 30, 2007, 2005, Requirement for Providing route of administration codes for Erythropoiesis stimulating agents.)

***CMS Publication 100-04 Medicare Claims Processing**, Transmittal 2033, Change Request 7064, Date: August 20, 2010

SUBJECT: End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services;

Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) requires implementation of an End Stage Renal Disease (ESRD) bundled prospective payment system (PPS) **effective January 1, 2011.**

The ESRD PPS will provide a single payment to ESRD facilities, i.e., hospital-based providers of services and renal dialysis facilities, that will cover all the resources used in providing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, training, and support services.

***50.2.1 - Drugs and Biologicals Included in the ESRD PPS**

(Rev. 2033, Issued: 08-20-10, Effective: 01-01-11, Implementation: 01-03-11)

With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related injectable drugs and biologicals and oral equivalents of those injectable drugs and biologicals are included in the ESRD PPS.

*If the renal dialysis facility needs to report a drug that was furnished to an ESRD beneficiary that was not related to the treatment of ESRD, they must include the **modifier AY** to indicate the item or service is not for the treatment of ESRD.*

ESRD-related drugs and biologicals that are currently separately paid under the basic case-mix composite rate payment system are considered in the calculation of any applicable outlier payment under the ESRD PPS.

Jurisdiction of claims for ESRD patients:

Hospital

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.

All hospital claims for ESRD related EPO with dates of service on or after January 1, 2007 are billed under revenue code 0636. Payment will be based on the ASP Pricing File.

Claims Processing Manual, Chapter 8, sections 60.4 and 60.7.

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

(Rev. 1503; Issued: 05-16-08; Effective Date: 10-01-08; Implementation Date: 10-06-08)

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.

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

(Rev. 2033, Issued: 08-20-10, Effective: 01-01-11, Implementation: 01-03-11)

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

***60.4.3.1 - Payment for Epoetin Alfa (EPO) in Other Settings**

(Rev. 2033, Issued: 08-20-10, Effective: 01-01-11, Implementation: 01-03-11)

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..

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.

Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department 60.7.3.2 (Rev. 1503; Issued: 05-16-08; Effective Date: 10-01-08; Implementation Date: 10-06-08)

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.

***60.7.3 - Payment Amount for Darbepoetin Alfa (Aranesp)**

(Rev. 2033, Issued: 08-20-10, Effective: 01-01-11, Implementation: 01-03-11)

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

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

(Rev. 2033, Issued: 08-20-10, Effective: 01-01-11, Implementation: 01-03-11)

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

Erythropoietin Stimulating Agents (ESAs) for End-Stage Renal Disease Related Anemia in a Renal dialysis Facility.

Background

Erythropoietin stimulating agents (ESA) are drugs used for anemia management for patients with renal disease. They are indicated in end stage renal disease (ESRD) patients and approved by the FDA to maintain hematocrit levels within a target range of 30-36 percent.

The original methodology for monitoring ESA claims was implemented with limited scientific analysis. It limits monitoring of ESAs to post-payment review based on a 90-day rolling average of claims. The target average hematocrit to trigger action was 37.5 percent, to provide recognition of naturally occurring variability in hematocrit levels. Additionally, higher levels could be maintained upon medical justification by the treating physician. This methodology and its revisions were issued through a series of temporary instructions.

In the fall of 2003, CMS solicited scientific information from the ESRD community in order to develop a permanent evidence-based policy for ESA monitoring. The scientific literature demonstrated that patients with hematocrit levels within the target range had better health outcomes than those with hematocrits below the target level. The data also demonstrated that there is considerable natural variability in individual patient hematocrit levels, making it difficult to consistently maintain a hematocrit within the narrow range of 33-36 percent.

In July 2004, CMS posted a proposed policy for monitoring of ESAs in patients with ESRD. CMS accepted formal public comment on the proposed policy until October 7, 2004. Additional public comments were presented and considered, including a consensus recommendation by the Kidney Care Partners. After considering all of the comments submitted, CMS issued a final policy, announced in CR 4135, that effective April 1, 2006 Medicare contractors will initiate monitoring of ESRD ESA claims when the hematocrit level reaches 39.0 (or hemoglobin of 13.0). For claims with hematocrit readings above the threshold of 39.0 (or hemoglobin above 13.0), the dose should be reduced by 25 percent over the preceding month. If the dose has been reduced by 25 percent,

dialysis facilities report modifier GS on the claim. Modifier GS was defined as “Dosage of EPO or Darbepoietin Alfa has been reduced 25% of preceding month’s dosage.”

When the GS modifier appears on the claim, Medicare contractors make payment based on the reported dosage. For claims with hematocrit levels above 39.0 (hemoglobin above 13.0) without modifier GS, Medicare contractors reduce the dosage payable by 25 percent of that reported on the claim.

Medicare contractors do make payment for dosage of EPO in excess of 500,000 IUs per month or dosage of Aranesp greater than 1500 mcg per month. If dosage exceeds these thresholds, Medicare contractors return the claim to the provider as a medically unbelievable error. (Now called Medically Unlikely Edits [MUEs]).

In October 2006, in response to public comments, CMS changed the definition of the GS modifier to “Dosage of EPO or Darbepoietin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level.”

Discussion

Since the last modification to this policy in October 2006, there have been several publications and an FDA “black box” that emphasize the risks facing ESRD patients who receive large doses of ESAs and have higher hematocrits. In response to those concerns, we are modifying this ESA monitoring policy to provide greater restrictions on the amount of ESAs for which payment is made at higher levels of hemoglobin.

Policy

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.

Effective for dates of service on or after January 1, 2008, for requests for payments or claims for ESAs for ESRD patients receiving dialysis in renal dialysis facilities and reporting a hematocrit level exceeding 39.0% (or hemoglobin exceeding 13.0g/dL) for 3 or more consecutive billing cycles immediately prior to and including the current billing cycle, the ESA dose for which payment may be made shall be reduced by 50% of the reported dose. In addition, claims must report modifiers ED or EE. Providers may continue to report the GS modifier when the reported hematocrit or hemoglobin levels exceed the monitoring threshold and a dose reduction has occurred. When the GS modifier is included on claims reporting modifier EE, the claim will be paid in full. The GS modifier, however, will have no effect on the 50% dosage reduction, or claims reporting modifier ED.

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. Effective for services provided on or after April 1, 2006, for claims reporting hematocrit or hemoglobin levels exceeding the monitoring threshold, the dose should be reduced by 25 percent 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 EPO or Darbepoietin 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 reported dose by 25% from that reported on the claim. 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.

Modifiers

Effective for dates of service 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) should also include modifier ED or EE. 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.”

Providers will report the GS modifier and the EE modifier when the reported hematocrit or hemoglobin levels exceed the monitoring threshold for less than 3 months and a dose reduction has occurred. When the recorded hematocrit or hemoglobin level exceeds the monitoring threshold for 3 or more consecutive billing cycles immediately prior to and including the current billing cycles, the provider will report the ED modifier and the claim will have an automatic 50% reduction in the reported dose applied, even if the claim also reports the GS modifier.

In addition, the medically unlikely edit (MUE) threshold has been revised. The MUE for claims for Epogen is reduced to 400,000 units from 500,000 and to 1200 micrograms from 1500 micrograms for Aranesp®. Claims reporting doses exceeding the new threshold are assumed to have typographical errors and will be returned to providers for correction.

Hct Exceeds 39.0% or Hgb Exceeds 13.0g/dL	ED Modifier? (Hct >39.0% or Hgb >13.0g ≥3 cycles)	EE Modifier? (Hct >39.0% or Hgb >13.0g <3 cycles)	GS Modifier? (Dosage reduced and maintained)	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%.

GS Modifier:

Medicare no longer requires value code 68 with dates of service on or after January 1, 2008. For claims with dates of service on or after January 1, 2008, Renal Dialysis Facilities (RDFs) will bill for each administration of EPO on a separate line indicating the line item date of service for the administration. The units reported on the claim line for EPO are multiplied by the total units defined by the HCPCS to reflect the dosage per administration. When RDFs report the GS modifier it is not required to be reported on every EPO line item. The GS modifier should be reported on the line item(s) that represent an administration of EPO at the reduced dosage following existing instructions in Publication 100-04 Medicare Claims Processing Manual, Chapter 8, Section 60.4. No payment reduction is made when the GS modifier is present on the claim

For ESRD beneficiaries, effective October 1, 2006, the GS modifier is defined as, "Dosage of EPO or Darbepoetin Alfa has been reduced and maintained in response to hematocrit or hemoglobin level." For dates of service October 1, 2006 and later, providers may report the GS modifier on facility inpatient claims when the dose of an erythropoietin analogue is reduced and maintained in response to a hematocrit or hemoglobin level. For dates of service October 1, 2006 and later, a claim reporting a GS modifier and a hematocrit above 39.0 (hemoglobin 13.0) will not have an automated 25% payment reduction applied. Certain situations may occur where a hematocrit/hemoglobin responsive dose reduction of an erythropoietin analogue occurred during one part of the billing cycle, but because of various reasons, the dose was increased during another part of the billing cycle. An example is when a patient missed treatments shortly after the dose was reduced and then returned to the dialysis facility late in the billing cycle with a low hematocrit/hemoglobin level. Providers may include the GS modifier on the claim for these situations. Providers are reminded that 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- 13.0g/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. (CMS Publication 100-4, Medicare Claims Processing Manual, Chapter 8, Sections 60.7 and 60.4)

Modifiers for Hematocrit Levels:

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.

Modifiers for Administration:

For dates of service on or after January 1, 2007, all providers are encouraged to include route of administration modifiers, **JA** for intravenous administration and **JB** for subcutaneous administration, on claims billing Q4081, J0882 for ESRD beneficiaries.

(CMS Publication 100-04, Medicare Claims Processing Manual, Transmittal No. 1212, Change Request #5480, March 30, 2007, 2005, Requirement for Providing route of administration codes for Erythropoiesis stimulating agents.)

Additional Coding Guidelines

Dialysis Patients:

For ESRD patients on dialysis, drug administered in dialysis facility (CMS Pub 100-4, Chapter 8, Sections 60.4 & 60.7):

- Type of Bill - 72X, 13X;
- The Hgb (value code 48) or HCT (value code 49) immediately prior to the billing period;
- Supplies - HCPCS A4657 on Revenue Code 270;
- There is no extra payment for the administration and the injection code should not be billed;

Skilled Nursing Facilities

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.

ESA services not related to dialysis are included in SNF consolidated billing.

ESA services related to dialysis are not included in the SNF Part A PPS rate and are excluded from consolidated billing.

When the patient is receiving dialysis it is an excluded service.

J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Major Category II. A. 3. - (Dialysis) Coding Applicable to EPO and Aranesp Services
J0886	Injection, epoetin alfa, 1,000 units (for ESRD on dialysis)	Major Category II. A. 3. - (Dialysis) Coding Applicable to EPO and Aranesp Services
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)	Major Category II. A. 3. - (Dialysis) Coding Applicable to EPO and Aranesp Services

From consolidated billing file for FI/A MAC

Hospice

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

Physician's Service

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.

Further information on jurisdiction

Some dialysis patients may choose either of two methods of payment for their epoetin alfa and dialysis equipment and supplies:

1. Method I patients receive their supplies from a renal dialysis facility (claims for these patients are processed by the Fiscal Intermediary, Part A).
2. Method II patients receive their supplies from a home dialysis supplier (claims for these patients are processed by the Durable Medical Equipment Regional Carrier {DMERC}).

**Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) eliminates method II home dialysis claims. All home dialysis claims must be billed by a renal dialysis facility and paid under the ESRD PPS. As a result, the submission of the CMS-382 form to the Medicare contractors is no longer required for home dialysis patients on or after January 1, 2011*

General Coding Guidelines

A. Reporting of Hematocrit and/or Hemoglobin Levels 80.8 -

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

Effective January 1, 2008, the following claims must report the most recent hematocrit or hemoglobin reading:

1. *All claims billing for the administration of an ESA (HCPCS J0881, J0882, J0885, J0886 and Q4081).*
2. *All claims for the administration of a Part B anti-anemia drug (other than ESAs) used in the treatment of cancer that are not self-administered.*

For institutional claims the hemoglobin reading is reported with a value code 48 and a hematocrit reading is reported with the value code 49. Claims not reporting a value code 48 or 49 will be returned to the provider.

For professional paper claims, test results are reported in item 19 of the Form CMS-1500 claim form. For electronic claims (837P), providers report the hemoglobin or hematocrit readings in Loop 2400 MEA segment. The specifics are MEA01=TR (for test results), MEA02=R1 (for hemoglobin) or R2 (for hematocrit), and MEA03=the test results.

Effective for dates of service on and after January 1, 2008, contractors will return paper and electronic professional claims when the most recent hemoglobin or hematocrit test results are not reported. Use Reason code 16 and Remark codes MA130 and N395 to return ESA service when the most recent hemoglobin or hematocrit test results are not submitted on the claim.

B. Required Modifiers for ESAs Administered to Non-ESRD Patients - 80.9

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

Effective January 1, 2008, all non-ESRD claims billing HCPCS J0881 and J0885 must begin reporting one of the following modifiers:

- EA:** *ESA, anemia, chemo-induced*
EB: *ESA, anemia, radio-induced*
EC: *ESA, anemia, non-chemo/radio*

ESAs administered for more than one of the indicated therapies are to be billed as separate line items (i.e., ESAs for chemo-induced anemia (EA modifier) are reported as separate line items (e.g., J0881EA);

ESAs for radio-induced anemia (EB modifier) are reported as separate line items (e.g., J0885EB);

ESAs for non-chemo/radio induced anemia (EC modifier) are reported as separate line items (e.g., J0881EC).

Only one of the three ESA modifiers may be reported at the line item level.

Institutional claims that do not report one of the above modifiers will be returned to the provider.

Professional claims that are billed without the required modifiers will be returned as unprocessable.

Use Reason code 4 and Remark code MA 130 to return ESA services billed without one of the required modifiers.

C. Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) shall be denied when any one of the following diagnosis codes is present on the claim:

- any anemia in cancer or cancer treatment patients due to folate deficiency (281.2),*
- B-12 deficiency (281.1, 281.3),*
- iron deficiency (280.0-280.9),*
- hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9-283.10, 283.19), or*
- bleeding (280.0, 285.1),*
- anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91); or*
- erythroid cancers (207.00-207.81).*

[80.12 – Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy (Rev. 1413; Issued: 01-14-08; Effective: 07-30-07; Implementation: 04-07-08)]

Intermediary Coding Guidelines

1. Guidelines for claims submitted on UB-04 to the Fiscal Intermediary

Providers should report the patient's principal admitting diagnosis in Form Locator (FL) 67 of the UB-04. Additional or secondary diagnoses may be recorded in FLs 67A – 67Q. For inpatient hospital claims subject to QIO review, the admitting diagnosis is required and should be recorded in FL 69. (See CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 25, Section 75 for additional instructions.)

Diagnostic tests, items and procedures are often ordered based on the patient's sign and/or symptom. When medical necessity for the service is justified by a sign or symptom that differs from the final diagnosis, the ICD-9-CM code for the sign or symptom is best reported

in Form Locator 76 on the UB-04 claim form. Diagnosis codes for signs or symptoms may also be indicated in fields 68-75. (See CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 3, Section 3.5.1.1 for additional instructions.)

Providers should report the patient's reason for visit (admitting diagnosis) on outpatient bills in Form Locator 76 of the UB-04. The patient's reason for visit information should be reported for all unscheduled outpatient visits when revenue codes 045X, 0516 or 0526 are present. The *ICD-9-CM* diagnosis code describing the patient's stated reason for seeking care (or as stated by the patient's representative) at the time of outpatient registration should be used. (See CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 3, Section 3.5.1.1 for additional instructions.)

For hospital inpatients:

- ESAs are included in the DRG;
- Drugs (including Darbepoetin alfa and Erythropoietin) are not covered for hospital inpatients who do not have Part A coverage.

In a skilled nursing facility (SNF):

- ESAs when administered by a renal dialysis facility, are covered under the Part B EPO benefit and are not included in the prospective payment rate for a Medicare covered SNF stay; (PUB 100-4, Chapter 6, Sections 0.2.1.1)
- ESAs when not part of the ESRD benefit are included in the prospective payment rate for a Medicare covered SNF stay [‘SNF HCPCS Help File,’ PUB 100-4, Chapter 6; MedLearn Memo Article SE0434, ‘Skilled Nursing Facility Consolidated Billing and Erythropoietin (EPO, Epoetin Alfa) and Darbepoetin Alfa (Aranesp).’]
- Skilled Nursing Facilities cannot be paid for Darbepoetin alfa administered to a non-ESRD beneficiary in a part B stay.

For ESRD patients:

Prior to 01/01/2011

- In a dialysis unit, ESAs are paid outside the composite rate;
- Dialyzing at home, Method I, ESAs are paid outside the composite rate to the dialysis facility;
- Dialyzing at home, Method II, ESAs are paid outside the composite rate.
 - If patients obtain their ESAs from a supplier, the supplier bills its DMERC.
 - If patients obtain their ESAs from a Medicare certified ESRD facility, the facility bills its Fiscal Intermediary.

After 01/01/2011

- *All ESRD-related injectable drugs and biologicals and oral equivalents of those injectable drugs and biologicals are included in the ESRD PPS.*

- *If the renal dialysis facility needs to report a drug that was furnished to an ESRD beneficiary that was not related to the treatment of ESRD, they must include the modifier AY to indicate the item or service is not for the treatment of ESRD.*
- *ESRD-related drugs and biologicals that are currently separately paid under the basic case-mix composite rate payment system are considered in the calculation of any applicable outlier payment under the ESRD PPS.*

With the implementation of the ESRD PPS, payment for all home dialysis services furnished to the ESRD beneficiary is made to a renal dialysis facility whether services were provided directly or under arrangements.

Section 153b of the Medicare Improvements for Patients and Providers Act (MIPPA) eliminates method II home dialysis claims. All home dialysis claims must be billed by a renal dialysis facility and paid under the ESRD PPS. As a result, the submission of the CMS-382 form to the Medicare contractors is no longer required for home dialysis patients on or after January 1, 2011

For hospice patients:

For hospice patients receiving ESAs for their terminal illness, payment is included in the hospice per diem rate.

For hospital outpatients:

For patients not on dialysis, ESAs are paid according to applicable payment system (OPPS or cost reimbursement);

For patients on dialysis, ESAs are paid per the ASP Pricing File prior to 01/01/2011. After 01/01/2011, for patients with ESRD who are on a regular course of dialysis, Aranesp or Epoetin alpha administered in a hospital outpatient department is paid the MMA Drug Pricing File rate

Revenue code 045x will no longer be required in order to allow for EPO and Aranesp payment for claims with dates of service on or after October 1, 2008. (Implementation Date: October 6, 2008) Medicare will allow for the payment of EPO and Aranesp when HCPCS code G0257 is present on the same claim when unscheduled and emergency dialysis treatments occur in the hospital outpatient setting.

For patients in a FQHC or RHC:

- ESAs furnished by a physician or non-physician practitioner in a FQHC or RHC, the costs of ESAs are allowable costs and are part of the clinic's all-inclusive rate calculation.
- Coverage limitations are unchanged.

RHCs or FQHCs

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 9, Section 100(B) states that *no type of technical services, such as...a technical component of a diagnostic or screening service, is ever billed on TOBs 71x or 73x..*

Technical services/components associated with professional services/components performed by independent RHCs or FQHCs are billed to Medicare carriers

Technical services/components associated with professional services/components performed by provider-based RHCs or FQHCs are billed by the base-provider on the TOB for the base-provider and submitted to the FI.

For dates of service on or after July 1, 2006, the following revenue codes should be used when billing for RHC or FQHC services, other than those services subject to the Medicare outpatient mental health treatment limitation or for the FQHC supplement payment...: 0521, 0522, 0524, 0525, 0527 and 0528 (See CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 9, Section 100[B].)

Critical Access Hospitals (CAHs)

Revenue codes 096X, 097X and 098X are to be used only by Critical Access Hospitals (CAHs) choosing the optional payment method (also called Option 2 or Method 2) and only for services performed by physicians or practitioners who have reassigned their billing rights. When a CAH has selected the optional payment method, physicians or other practitioners providing professional services at the CAH may elect to bill their carrier or assign their billing rights to the CAH. When professional services are reassigned to the CAH, the CAH must bill the FI using revenue codes 096X, 097X or 098X.

Other

Per CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 9, Section 100(B), only four types of services are billed on TOBs 71X and 73X: Professional or primary services not subject to the Medicare outpatient mental health treatment limitation are bundled into line item(s) using revenue code 052X; services subject to the Medicare outpatient mental health treatment limitation are billed under revenue code 0900 (previously 0910); ...telehealth originating site facility fees under revenue code 0780 [and] FQHC supplemental payments are billed under revenue code 0519, effective for dates of service on or after 01/01/2006.

Procedure codes may be subject to Correct Coding Initiative (CCI) edits or OPPS packaging edits. Please refer to CCI and OPPS requirements prior to billing Medicare.

Prior to 01/01/2011:

When an ESRD beneficiary is given erythropoietin outside of the ESRD facility or provider setting, it is presumed to be administered by the beneficiary's monthly capitation payment (MCP) physician or his/her staff as "incident to" such physician's services. Payment for the administration of erythropoietin to dialysis patient is included in the physicians' MCP, and also may not be paid to another (non-MCP) provider. Although, an additional allowance for the administration of erythropoietin may not be made, the patient's MCP physician or a physician other than the MCP physician may be paid for the drug itself.

Hospitals Billing for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Non-ESRD Patients - 80.10 (Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

For patients with chronic renal failure who are not yet on a regular course of dialysis, EPO and Aranesp administered in a hospital and billed as an outpatient service on type of bill 13x or inpatient Part B bill type 12x are paid under the Outpatient Prospective Payment System (OPPS). Non-OPPS hospitals are paid on reasonable charges.

Hospitals report charges under revenue code 0636. For EPO, hospitals report charges under revenue code 0636 with HCPCS code J0885 effective January 1, 2006. Aranesp is reported with HCPCS code J0881 effective January 1, 2006.

C. Carrier Coding Instructions

1. If the initial dose of an ESA was administered in another setting (i.e. hospital, in a state outside our jurisdiction, or in another facility); subsequent office-administered ESA claims must include documentation that the initially administered ESA met coverage criteria, as set forth in the “Indications and limitations of Coverage, and/or Medical Necessity” section of the policy. This means that the patient’s history and previous work-up including lab work at another site should support the continuation of this drug. The current work-up should include testing to support the need to continue the drug.
Initial information must be available for all claims for post-payment review. If the patient has had transfusion(s) or another exception this is best handled by a physician summarizing why the patient's lab values may be skewed.
2. When billing for the administration of an ESA, use the applicable therapeutic injection codes only. CPT code 99211 is not acceptable if the only service is the injection. If a brief E/M service is provided bill 99211 with the drug code but do not bill the therapeutic injection codes with code 99211.
3. If an electronic submitter has additional documentation, which Medicare may require, they can indicate: “DOCUMENTATION AVAILABLE UPON REQUEST” in the narrative (NTE02) segment. If the additional documentation you have is needed for Medicare to make its payment determination, a development letter will be sent requesting the information. If the NTE02 segment does not indicate the availability of the additional documentation or the information is not returned in a timely manner, the claim will be returned as unprocessable.
4. The following information must be submitted with each claim:
 - a. For 4010A1 electronic format.
The ICD-9 code for the cause of the anemia must be placed in 2300 Loop, HI Segment for electronic claims (item 21, #1 for CMS 1500 forms) and a pointer of 1 in Loop 2400, SV1 segment for electronic claims (#1 in item 24E on the CMS 1500 form).
 - b. HCT or Hgb values – see above
 - c. Multiple doses of EPO may be included as a single line item.
 - Enter the number of units administered in item 24G.
The standard unit for EPO is 1,000 units.
 - Enter "1" in item 24G for every 1,000 units administered.
 - When the dosage is not an even multiple of 1,000, units must be rounded. For dosages 1 to 499, round down. For dosages 500 to 999, round up to the next 1,000 units.
Example: If 12,100 units were given, enter 12 as the units administered.
 - d. Dates may be spanned for a maximum of 7 days per line item.
5. There are two code options available to bill for EPO. The patient's diagnosis is the determining factor in code submission.
 - a. For ESRD on dialysis, use the code J0886 per 1000units.
 - b. For other diagnoses, use code J0885 (non-ESRD on dialysis) per 1000 U.

6. Coding Guidelines for darbepoetin alfa J0881, J0882

- a. For ESRD on dialysis, use the code J0882 per 1mcg.
- b. For indications other than ESRD on dialysis use J0881-Injection darbepoetin alfa, per 1mcg
- c. Darbepoetin alfa is available in microgram (mcg) dosages (EPO is available in unit dosages)
Enter the number of mcgs administered in item 24G.
 - The standard unit for darbepoetin is 1mcg.
Enter "1" in the item 24G for every 1mcg

7. Claims for anemia of chronic disease (285.29) for EPO or DPA

Prepayment documentation is no longer required for claims payment. Claims submission is as above for all uses of these agents. A secondary diagnosis is required to indicate the underlying disease.

Documentation in the progress notes should indicate the chronic disease associated with the anemia with a discussion as to the work-up of the anemia and a justification of the use of ESAs to treat the anemia. This information should be available upon request.

Laboratory work up

- Hgb and /or HCT
- Red blood cell indices
- erythropoietin level
- serum iron,
- iron-binding capacity
- serum ferritin and/or bone marrow iron stain results

Revision Effective Date

07/16/2012

Revision History

06/01/2012 -This guideline is effective for J-8 providers in Michigan MAC B 07/16/12, Michigan MAC A 07/23/12, Indiana MAC A 07/23/12 and Indiana MAC B 08/20/12.