| CMS Manual System | **Department of Health & Human Services (DHHS)** |
|---|---|
| Pub 100-04 Medicare Claims Processing | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 1041** | **Date: AUGUST 25, 2006** |
| | **Change Request 5216** |

NOTE: Transmittal 1007, dated, July 28, 2006 is rescinded and replaced with Transmittal 1041, dated August 25, 2006. The original change request changed the revenue code that hospitals reported EPO with to 0636, however, that is not the case, so they will continue to use 634/635 as they currently are doing. This information is being removed from Pub 100-04, chapter 8 and changes were made to business requirements 5216.3, 5216.4, 5216.4.1, 5216.4.2, 5216.5, 5216.5.1 and 5216.5.2. ESRD EPO will stay exactly the same with the exception of using the new code Q4081 code instead of the current J0886 beginning in January. All other information remains the same.

**Subject: Change in Healthcare Common Procedure Coding System (HCPCS) for Renal Dialysis Facilities and Hospitals Billing for End Stage Renal Disease (ESRD) Related Epoetin Alfa (EPO) Effective January 1, 2007**

**I. SUMMARY OF CHANGES:** A new HCPCS code has been established for an injection of epoetin alfa, 100 units for ESRD patients on dialysis. Renal dialysis facilities and hospitals will begin using the new 100 unit code effective January 1, 2007. In addition, hospital instructions previously provided in PM 2503 are being manualized with this instruction.

**New / Revised Material**
**Effective Date: January 1, 2007**
**Implementation Date: January 2, 2007**

*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/ Table of Contents |
| R | 4/210/ Hospital Services for Patients with End Stage Renal Disease (ESRD) |
| R | 8/ Table of Contents |
| R | 8/10/10.5 Hospital Services |
| R | 8/60/60.4.1 / Epoetin Alfa (EPO) Facility Billing Requirements |
| R | 8/60/60.4.3 / Payment for Epoetin Alfa (EPO) in Other Settings |
| R | 8/60/60.4.3.2 / Epoetin Alfa (EPO) Provided in the Hospital Outpatient Departments |
| R | 8/60/60.7.1/ Darbepoetin Alfa (Aranesp) Facility Billing |

|   | Requirements |
|---|---|
| **R** | 8/60/60.7.3/ Payment for Darbepoetin Alfa (Aranesp) in Other Settings |
| **R** | 8/60/60.7.3.2/ Payment for Darbepoetin Alfa (Aranesp) in the Hospital Outpatient Department |

**III. FUNDING:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 operating budgets.

**IV. ATTACHMENTS:**

**Business Requirements**

**Manual Instruction**

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

# Attachment - Business Requirements

| Pub. 100-04 | Transmittal: 1041 | Date: August 25, 2006 | Change Request 5216 |
|---|---|---|---|

NOTE: Transmittal 1007, dated, July 28, 2006 is rescinded and replaced with Transmittal 1041, dated August 25, 2006. The original change request changed the revenue code that hospitals reported EPO with to 0636, however, that is not the case, so they will continue to use 634/635 as they currently are doing. This information is being removed from Pub 100-04, chapter 8 and changes were made to business requirements 5216.3, 5216.4, 5216.4.1, 5216.4.2, 5216.5, 5216.5.1 and 5216.5.2. ESRD EPO will stay exactly the same with the exception of using the new code Q4081 code instead of the current J0886 beginning in January. All other information remains the same.

**SUBJECT: Change in Healthcare Common Procedure Coding System (HCPCS) for Renal Dialysis Facilities and Hospitals Billing for End Stage Renal Disease (ESRD) Related Epoetin Alfa (EPO) Effective January 1, 2007.**

## I. GENERAL INFORMATION

**A. Background:** A new HCPCS code has been established for an injection of epoetin alfa, 100 units for ESRD patients on dialysis. The new code, Q4081 will be effective January 1, 2007. Renal dialysis facilities and hospitals should discontinue using the code J0886 and begin using the code Q4081 for claims with dates of service on or after January 1, 2007.

**B. Policy:** Renal dialysis facilities and hospitals billing for an injection of epoetin alfa for ESRD patients on dialysis shall begin using the new code Q4081 for all claims with dates of service on or after January 1, 2007.

## II. BUSINESS REQUIREMENTS

*"Shall" denotes a mandatory requirement*
*"Should" denotes an optional requirement*

| Requirement Number | Requirements | Responsibility ("X" indicates the columns that apply) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | FI | RHHI | Carrier | DMERC | Shared System Maintainers | | | | Other |
| | | | | | | FISS | MCS | VMS | CWF | |
| 5216.1 | Medicare Systems shall modify existing edits for Epoetin Alfa to require the new code Q4081 in replace of J0886 for bill types 72x, 12x, 13x and 85x with dates of service on or after 1/1/07. | | | | | X | | | | |

| Requirement Number | Requirements | Responsibility ("X" indicates the columns that apply) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | FI | RHHI | Carrier | DMERC | Shared System Maintainers | | | | Other |
| | | | | | | FISS | MCS | VMS | CWF | |
| 5216.2 | Medicare Systems shall ensure that the payment calculation for bill type 72x is adjusted to apply the rate for Q4081 for each 100 units reported with the value code 68. | | | | | X | | | | |
| 5216.3 | Medicare contractors shall apply the same billing and payment guidelines for Q4081 as required for J0886 in Claims Processing Manual Pub.100-04, Chapter 8, Section 60.4. | X | | | | X | | | | |

## III. PROVIDER EDUCATION

| Requirement Number | Requirements | Responsibility ("X" indicates the columns that apply) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | FI | RHHI | Carrier | DMERC | Shared System Maintainers | | | | Other |
| | | | | | | FISS | MCS | VMS | CWF | |
| 5216.4 | A provider education article related to this instruction will be available at 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 in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | | | | | | | | |

## IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

### A. Other Instructions: N/A

| X-Ref Requirement # | Instructions |
|---|---|
| | |

### B. Design Considerations: N/A

| X-Ref Requirement # | Recommendation for Medicare System Requirements |
|---|---|
| | |

### C. Interfaces: N/A

### D. Contractor Financial Reporting /Workload Impact: N/A

**E. Dependencies:** Dependent on the publication of the new code.

### F. Testing Considerations: N/A

## V. SCHEDULE, CONTACTS, AND FUNDING

| | |
|---|---|
| **Effective Date***: January 1, 2007<br><br>**Implementation Date:** January 2, 2007<br><br>**Pre-Implementation Contact(s):**<br>Wendy.Tucker@cms.hhs.gov, 410-786-3004 or<br>Jason.Kerr@cms.hhs.gov, 410-786-2123<br><br>**Post-Implementation Contact(s):** Appropriate RO. | **No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.** |

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

# Medicare Claims Processing Manual
## Chapter 4 - Part B Hospital
## (Including Inpatient Hospital Part B and OPPS)

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**Table of Contents**

***(Rev. 1041, 08-25-06)***

*210 – Hospital Services For Patients with End Stage Renal Disease (ESRD)*

## *210 - Hospital Services For Patients with End Stage Renal Disease (ESRD)*

***(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)***

Effective with claims with dates of service on or after August 1, 2000, hospital-based ESRD facilities must submit ESRD dialysis and those items and services directly related to dialysis (e.g., drugs, supplies) on a separate claim from services not related to ESRD. Items and services not related to the dialysis must be billed by the hospital using the hospital bill type. ESRD related services use the ESRD bill type. This requirement is necessary to properly pay the unrelated ESRD services under OPPS.

*Generally, Medicare does not allow payment under the OPPS for routine dialysis treatments furnished to End Stage Renal Disease (ESRD) patients in the outpatient department of a hospital that does not have a certified dialysis facility. However, in certain medical situations in which the ESRD patient cannot obtain her or his regularly scheduled dialysis treatment at a certified ESRD facility, the OPPS rule for 2003 allows payment for non-routine dialysis treatments furnished to ESRD patients in the outpatient department of a hospital that does not have a certified dialysis facility. Payment is limited to unscheduled dialysis for ESRD patients in the following circumstances:*

- *Dialysis performed following or in connection with a vascular access procedure;*
- *Dialysis performed following treatment for an unrelated medical emergency; e.g., if a patient goes to the emergency room for chest pains and misses a regularly scheduled dialysis treatment that cannot be rescheduled, we allow the hospital to provide and bill Medicare for the dialysis treatment; or*
- *Emergency dialysis for ESRD patients who would otherwise have to be admitted as inpatients in order for the hospital to receive payment.*

*In these situations, non-ESRD certified hospital outpatient facilities are to bill Medicare using a new Healthcare Common Procedure Coding System (HCPCS) code, G0257 - Unscheduled or emergency treatment for dialysis for ESRD patient in the outpatient department of a hospital that does not have a certified ESRD facility.*

# Medicare Claims Processing Manual

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

Table of Contents

*(Rev.1041, 08-25-06)*

*10.5 – Hospital Services*

## *10.5 - Hospital Services*

***(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)***

*Outpatient dialysis services for a patient with acute kidney failure or chronic kidney failure but not eligible for Medicare under the ESRD provisions at the time services are rendered must be billed by the hospital and cannot be billed by a Medicare certified renal dialysis facility on bill type 72x.*

*Hospitals with a Medicare certified renal dialysis facility should have outpatient ESRD related services billed by the hospital-based renal dialysis facility on bill type 72x. Hospitals that do not have a Medicare certified renal dialysis facility may bill for outpatient emergency or unscheduled dialysis services. The composite rate is not paid. For more information regarding the outpatient hospital billing policy for ESRD related services, see chapter 4 section 210 of this manual.*

When an individual is furnished outpatient hospital services and is thereafter admitted as an inpatient of the same hospital due to renal failure - within 24 hours for non PPS hospitals and within 72 hours for PPS hospitals - the outpatient hospital services furnished are treated as inpatient services unless the patient does not have Part A coverage. Charges are reported on Form CMS-1450. The day on which the patient is formally admitted as an inpatient is counted as the first inpatient day. The composite rate is not paid.

## 60.4.1 - Epoetin Alfa (EPO) Facility Billing Requirements

***(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)***

*Revenue codes required for reporting EPO:*

| *Revenue Codes* | *Dates of Service* | | | |
|---|---|---|---|---|
| | *Bill Type 72x* | *Bill Type 12x* | *Bill type 13x* | *Bill type 85x* |
| *0634 – administrations under 10,000 units* | *1/1/04 – present* | *4/1/06 – present* | *1/1/04 – present* | *1/1/04 – present* |
| *0635 – administrations of 10,000 units or more* | *1/1/04 – present* | *4/1/06 – present* | *1/1/04 – present* | *1/1/04 – present* |
| *0636 – detailed drug coding* | *N/A* | *1/1/04 – 3/31/06* | *N/A* | *N/A* |

*For additional hospital billing instructions related to bill types 12x, 13x and 85x see also sections 60.4.3.1 and 60.4.3.2 of this chapter.*

The HCPCS code for EPO must be included:

| *HCPCS* | *HCPCS Description* | *Dates of Service* |
|---|---|---|
| *Q4055* | *Injection, Epoetin alfa, 1,000 units (for ESRD on Dialysis)* | *1/1/2004 through 12/31/2005* |
| *J0886* | *Injection, Epoetin alfa, 1,000 units (for ESRD on Dialysis)* | *1/1/2006 through 12/31/2006* |
| *Q4081* | *Injection, Epoetin alfa, 100 units (for ESRD on Dialysis)* | *1/1/2007 to present* |

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

The hematocrit reading taken prior to the last administration of EPO during the billing period must also be reported on the UB-92/Form CMS-1450 with value code 49. Effective January 1, 2006 the definition of value code 49 used to report the hematocrit reading is changed to indicate the patient's most recent hematocrit reading taken **before** the start of the billing period.

The hemoglobin reading taken during the billing period must be reported on the UB-92/Form CMS-1450 with value code 48. Effective January 1, 2006 the definition of value code 48 used for the hemoglobin reading is changed to indicate the patient's most recent hemoglobin reading taken **before** the start of the billing period.

*To report a hemoglobin or hematocrit reading for a new patient on or after January 1, 2006, the provider should report the reading that prompted the treatment of epoetin alfa. The provider may use results documented on form CMS 2728 or the patient's medical records from a transferring facility.*

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

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

***(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)***

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

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

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

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

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

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

***(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)***

When ESRD patients come to the hospital for a medical emergency their dialysis related anemia may also require treatment. 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*. Effective for claim dates of service on or after January 1, 2006, hospitals are no longer required to report the value code 49 on the 13x and 85x bill types.

## 60.7.1 – Darbepoetin Alfa (Aranesp) Facility Billing Requirements

***(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)***

Revenue code 0636 is used to report *Aranesp.*

The HCPCS code for aranesp must be included:

| *HCPCS* | *HCPCS Description* | *Dates of Service* |
|---|---|---|
| *Q4054* | *Injection, darbepoetin alfa, 1mcg (for ESRD on Dialysis)* | *1/1/2004 through 12/31/2005* |
| *J0882* | *Injection, darbepoetin alfa, 1mcg (for ESRD on Dialysis)* | *1/1/2006 to present* |

The hematocrit reading taken prior to the last administration of Aranesp during the billing period must also be reported on the UB-92/Form CMS-1450 with value code 49.

Effective January 1, 2006 the definition of value code 49 used to report the hematocrit reading is changed to indicate the patient's most recent hematocrit reading taken **before** the start of the billing period.

*To report a hematocrit reading for a new patient on or after January 1, 2006, the provider should report the reading that prompted the treatment of darbepoetin alfa. The provider may use results documented on form CMS 2728 or the patient's medical records from a transferring facility.*

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

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

***(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)***

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

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

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

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

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

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

***(Rev. 1041, Issued: 08-25-06; Effective: 01-01-07; Implementation: 01-02-07)***

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

Hospitals use bill type 13X *(or 85X for Critical Access Hospitals*) and report charges under revenue code 0636. The total number of units as a multiple of 1mcg is placed in the unit field. Value code 49 must be reported with the hematocrit value for the hospital outpatient *visits prior to January 1, 2006*. Effective for claim dates of service on or after January 1, 2006, hospitals are no longer required to report the value code 49 on the 13x and 85x bill types.