CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 146 **Date: APRIL 23, 2004**

CHANGE REQUEST 3176

I. SUMMARY OF CHANGES: Clarification of billing procedures for separately billable ESRD injectable drugs and the administration-supply charges. Correction to Provider Series Number for Dialysis Providers: 3300-3399 Children's Hospitals. Clarification of drug payment amounts for facilities.

NEW/REVISED MATERIAL - EFFECTIVE DATE: October 1, 2004
***IMPLEMENTATION DATE: October 4, 2004**

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 only receive the new/revised information, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	8/10.9/ Dialysis Provider Number Series
R	8/60.2/ Drugs Furnished in Dialysis Facilities
R	8/60.2.1/ Billing Procedures for Drugs for Facilities
N	8/60.2.1.1/ Separately Billable ESRD Drugs
R	8/60.2.2/ Drug Payment Amounts for Facilities

***III. FUNDING:**

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-04	Transmittal: 146	Date: April 23, 2004	Change Request 3176

SUBJECT: Clarification of Billing for Separately Billable ESRD Drugs

I. GENERAL INFORMATION

A. Background: Multiple categories of drugs are not included in the ESRD composite rate. These drugs are considered to be separately billable drugs when used to treat the patient's renal condition. The separately billable injectable drugs allow for an administration-supply charge. The allowable administration-supply charges are determined by the most appropriate method of administration.

B. Policy: Separately billable drugs furnished in ESRD dialysis centers must be of the appropriate category of drugs. The most appropriate method of administration-supply will be paid for these separately billable injectable drugs.

C. Provider Education: "A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn 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 one week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin."

II. BUSINESS REQUIREMENTS

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

Requirement #	Requirements	Responsibility
3176.1	The contractor shall pay for separately billable drugs **furnished in independent dialysis facilities** when they are in one of the following categories: Antibiotics* Muscle relaxants Analgesics Sedatives Anabolics Tranquilizers Hematinics Thrombolytics: used to declot central venous catheters *** Exception: Included in the composite rate when used at home by a patient to treat an infection of the catheter site or peritonitis**	FI

	associated with peritoneal dialysis.	
3176.1.1	The contractor shall pay for separately billable drugs furnished in independent dialysis facilities, based on the lower of: billed charges or 95 percent Average Wholesale Price (AWP) for the calendar year 2004.	FI
3176.1.2	The contractor shall calculate coinsurance based on the billed charges of separately billable drugs furnished in independent dialysis facilities.	FI
3176.1.3	The contractor shall apply the Medicare deductible based on the billed charges for separately billable drugs furnished in independent dialysis facilities.	FI
3176.2	The contractor shall pay for separately billable drugs **furnished in hospital-based facilities** when they are in one of the following categories: Antibiotics* Muscle relaxants Analgesics Sedatives Anabolics Tranquilizers Hematinics Thrombolytics: used to declot central venous catheters *** Exception: Included in the composite rate when used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis.**	FI
3176.2.1	The contractor shall pay for separately billable drugs furnished in hospital-based facilities at cost.	FI
3176.2.2	The contractor shall calculate coinsurance based on the cost of separately billable drugs furnished in hospital-based facilities.	FI
3176.2.3	The contractor shall apply the Medicare deductible to separately billable drugs based on the cost of separately billable drugs furnished in hospital-based facilities.	FI
3176.3	The contractor shall accept bills for separately billable drugs furnished in either an independent dialysis or hospital-based facility with the following data: • Type of bill = 72x. • Revenue code 0636, "Drugs Requiring Specific Information." • HCPCS code that indicates the lowest	FI

	common denominator for the dosage. • The units field is used as a multiplier to arrive at the dosage amount.	
3176.3.1	The contractor shall pay HCPCS A4657 (Injection administration-supply charge) for separately billable injectable drugs when the most appropriate method of administration is with a syringe, alcohol pad, and gloves. Co-payments and deductibles are applicable.	FI
3176.3.2	The contractor shall pay HCPCS A4913 (IV administration-supply charge) for separately billable injectable drugs when the most appropriate method of administration is with a IV solution administration set, syringe, alcohol pad, and gloves. Co-payments and deductibles are applicable.	FI

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions
CR 2963 CR 2984	Erythropoietin replacement therapies are separately billable but are paid according to established methodology.

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: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: October 1, 2004 **Implementation Date:** October 4, 2004 **Pre-Implementation Contact(s):** Pat Barrett, 410-786-0508 **Post-Implementation Contact(s)**: Appropriate Regional Office	These instructions should be implemented within your current operating budget.

Medicare Claims Processing Manual

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

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(Rev. 146, 04-23-04)

60.2.1.1 - Separately Billable ESRD Drugs

10.9 – Dialysis Provider Number Series

(Rev. 146, 04-23-04)

There are multiple facilities that provide dialysis services to ESRD beneficiaries. To ensure that provider data is correct, facilities are required to use a Provider Number based on facility type issued by CMS.

The Provider Number Series for Dialysis Providers are as follows:

2300-2499	Chronic Renal Dialysis Facilities (Hospital – Based)
2500-2899	Non – Hospital Renal Facilities
2900-2999	Independent Special Purpose Renal Dialysis Facility
3300-3399	Children's Hospitals (Excluded from PPS)
3500-3699	Renal Disease Treatment Centers (Hospital Satellites)
3700-3799	Hospital Based Special Purpose Renal Dialysis Facilities

All facilities should use their appropriately assigned provider numbers on the 72x type of bill. In the event that a facility changes from one type to another, the provider number must reflect the facility's present provider type.

Listings of the Provider Numbers Series may be found in the "National Listing of Medicare Providers Furnishing Kidney Dialysis and Transplant Services". Two Web sites provide this information: http://cms.hhs.gov/esrd/8.asp and http://cms.hhs.gov/esrd/8e.pdf.

60.2 - Drugs Furnished in Dialysis Facilities

(Rev. 146, 04-23-04)

Payment is made for drugs furnished in independent dialysis facilities, and paid outside the composite rate, based on the lower of billed charges or *95 percent Average Wholesale Price (AWP) for the calendar year 2004*. Coinsurance and deductible are applied to *billed* charges.

Hospital-based facilities are paid *at cost with applicable coinsurance and deductibles.* See the Medicare Benefit Policy Manual, Chapter 11 for a description of drugs that are part of the composite rate and when other drugs may be covered.

Except for EPO *and Darbepoetin Alfa (Aranesp)*, (see §60.4), drugs and biologicals, such as blood, may be covered in the home dialysis setting only if the "incident to a physician's services" criteria are met (i.e., it is not covered under the composite rate). Normally, a physician is not in the patient's home when the drugs or biologicals are administered, and therefore, drugs and biologicals generally are not paid in the home setting.

60.2.1 - Billing Procedures for Drugs for Facilities

(Rev. 146, 04-23-04)

The following billing procedures apply to independent and hospital based facilities.

Facilities identify and bill for drugs by HCPCS code, along with revenue code 0636, "Drugs Requiring Specific Information." Example below includes the HCPCS code and indicates the dosage amount specified in the descriptor of that code. Facilities use the units field as a multiplier to arrive at the dosage amount.

EXAMPLE

HCPCS	Drug	Dosage (lowest denominator)	Amount
J3360	Valium	5 mg	$2.00

Actual dosage, 10 mg

On the bill, the facility shows J3360 and 2 in the units field (2 x 5 mg = 10 mg). For independent facilities, FIs compare the price of $4.00 (2 x $2.00) to the billed charge and pay the lower, subject to coinsurance and deductible.

NOTE: When the dosage amount is greater than the amount indicated for the HCPCS code, the facility rounds up to determine units. *When the dosage amount is less than the amount indicated for the HCPCS code, use one as the unit of measure.* In the example above, if the dosage were 7 mg, the facility would show 2 in the unit field*, if the dosage were 3 mg, the facility would show 1 in the unit field.*

Facilities bill for supplies used to administer drugs with revenue code 0270, "Medical/Surgical Supplies." The number of administrations is shown in the units field.

EXAMPLE

Revenue Code	Units
0270	3

The number of units for supply codes billed should match the number of injections billed on the claim form.

Appropriate HCPCS codes for administration-supply of separately billable drugs would include:

A4657: Injection Administration-supply Charge: include the cost of alcohol swab, syringe, and gloves.

A4913: IV Administration-supply Charge: include the cost of IV solution administration set, alcohol swab, syringe, and gloves. This code should only be used when an IV solution set is required for a drug to be given. This rate will not be paid for drugs that only require a syringe for administration.

60.2.1.1 – Separately Billable ESRD Drugs

(Rev. 146, 04-23-04)

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: Epotein Alfa (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.

60.2.2 - Drug Payment Amounts for Facilities

(Rev. 146, 04-23-04)

Hospital-based facilities are paid *at cost with applicable coinsurance and deductibles.* Independent facilities are paid based on *the lower of billed charges or 95 percent AWP for the calendar year 2004: coinsurance and deductibles are applied to billed charges.* See Chapter 17 for a complete description of drug pricing.

Payment for separately billable ESRD drugs is subject to the Medicare policy that the program does not pay for items that are not medically necessary, or pay for the cost of luxury items beyond the basic item required to treat the patient's medical condition. Therefore, payment is limited to the reimbursement that would be made for the generic form of the drug or the lowest cost equivalent drug. Payment for the additional price of a brand name drug in excess of the price of the generic drug may be made only if the FI determines that the brand name drug is medically necessary.