Medicare Learning Network
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Information for Medicare Fee-For-Service Health Care Professionals

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Clarification of Billing for Separately Billable End Stage Renal Disease Drugs

Note: Note: This article was updated on May 7, 2013, to reflect current Web addresses. This article was previously revised on December 2, 2011, to add a reference to MM7471 (http://www.cms.gov/MLNMattersArticles/downloads/MM7471.pdf) to advise providers that CMS is eliminating the ESRD PPS-related outlier Part B Drug-Specific List to allow all non-composite rate ESRD-related drugs with a HCPCS and an ASP rate to be eligible for the outlier payment. All other information remains unchanged.

Provider Types Affected

Hospital-based and independent dialysis facilities

Provider Action Needed


STOP – Impact to You

This instruction clarifies the billing procedures for separately billable End Stage Renal Disease (ESRD) injectable drugs and administration-supply charges. It also includes a correction to the provider series numbers for dialysis providers: 33003399 (Children's Hospitals Excluded from PPS).


CAUTION – What You Need to Know

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


GO – What You Need to Do

Refer to the *Background* and *Additional Information* sections of this article for further details regarding these changes.

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.

This instruction clarifies the billing procedures for separately billable ESRD injectable drugs and administration-supply charges. Separately billable drugs furnished in ESRD dialysis centers must be of the appropriate category of drugs, and the most appropriate method of administration-supply will be paid for these separately billable injectable drugs. The instruction also includes corrections to the provider series numbers for dialysis providers: 3300-3399 (Children's Hospitals).

Separately Billable ESRD Drugs

The following categories of drugs are separately billable when furnished in hospital-based facilities or independent dialysis facilities to treat the patient's renal condition:

- Antibiotics
- Analgesics
- Anabolics
- Hematinics
- Muscle relaxants
- Sedatives
- Tranquilizers
- 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) and Darbepoetin Alfa (Aranesp) (see the *Medicare Claims Processing Manual, Pub. 100-04, Sections 60.4* and *60.7*). Also, note that there is an exception for separate payment for antibiotics. Antibiotics are 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.

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.

Drugs Furnished in Dialysis Facilities

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 (CY) 2004.

Coinsurance and deductible are applied to billed charges.

Hospital-based facilities are paid at cost with applicable coinsurance and deductibles.

The *Medicare Benefit Policy Manual, Chapter 11* provides a description of drugs that are part of the composite rate and when other drugs may be covered. Except for Epoetin Alfa (Epogen, EPO) and Darbepoetin Alfa (Aranesp, DPA), 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.

Billing Procedures for Drugs for Facilities

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." The example below includes the Healthcare Common Procedure Coding System (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 1: HCPCS – J3360, Drug – Valium, Dosage (lowest denominator) – 5mg, Amount - $200.

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, fiscal intermediaries (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 (1) as the unit of measure.

In the above example, 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 one (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 2: Revenue Code - 0270, Units - 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.

Drug Payment Amounts for Facilities

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. 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.

Dialysis Provider Number Series

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 the Centers for Medicare & Medicaid Services (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. Providers may want to visit the website that has information on where the dialysis facilities are located, how big they are, and how long they have been in business at http://www.cms.gov/Center/Special-Topic/End-Stage-Renal-Disease-ESRD-Center.html on the CMS website.

Related Instructions

Transmittal 39 (Change Request (CR) 2963) dated January 6, 2004, Change in Coding on Medicare Claims for Darbepoetin Alfa (trade name Aranesp) and Epoetin Alfa (trade name Epogen, EPO) for Treatment of Anemia In End Stage Renal Disease (ESRD) Patients On Dialysis, can be found at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R39OTN.pdf on the CMS website.

Also, Transmittal 118 (Change Request (CR) 2984) dated March 5, 2004, Frequency Limitations for Darbepoetin Alfa (trade name Aranesp) for Treatment of Anemia in End Stage Renal Disease (ESRD) Patients on Dialysis, can be found at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R118CP.pdf on the CMS website.

Additional Information

As a result of these changes, the following Sections are being revised or added to the Medicare Claims Processing Manual, Pub. 100-04, Chapter 8 (Outpatient ESRD Hospital, Independent Facililty, and Physician/Supplier Claims):

- 10.9 - Dialysis Provider Number Series – revised
- 60.2 - Drugs Furnished in Dialysis Facilities – revised
- 60.2.1 - Billing Procedures for Drugs for Facilities – revised
- 60.2.1.1 - Separately Billable ESRD Drugs – new
- 60.2.2 - Drug Payment Amounts for Facilities – revised.

These revised manual sections can be viewed as an attachment to CR 3176. The official instruction issued to your intermediary regarding this change may be found

by going to *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R146CP.pdf* on the CMS website.

MM3176 was revised on April 13, 2007, to delete a sentence on page 2 regarding the payment basis for separately billable supplies. Previously, this article was revised on August 24, 2006, to delete mention in the "Caution" section regarding payment methodology. For payment information, please see CR3451 at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R3183CP.pdf on the CMS site.If you have any questions, please contact your carrier/intermediary at their toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.