Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

Table of Contents

Crosswalk to Old Manuals

10 - Payment Rules for Drugs and Biologicals....2

20 - Payment Allowance Limit for Drugs and Biologicals....8

20.1 - Single Drug Pricer (SDP) 8

20.2 - Calculation of the AWP....11

20.3 - Detailed Procedures for Determining AWPs and the Drug Payment Allowance Limits....12

20.3.1 - Background....12

20.3.2 - Review of Sources for Medicare Covered Drugs and Biologicals12

20.3.3 - Use of Generics 13

20.3.4 - Find the Strength and Dosage....13

20.3.5 - Restrictions 14

20.3.6 - Inherent Reasonableness for Drugs and Biologicals 14

30 - Carrier Distribution of Limit Amounts....15

40 - Discarded Drugs and Biologicals 16

50 - Assignment Required for Drugs and Biologicals 17

60 - License Required to Dispense Drugs....20

70 - Claims Processing Requirements - General 21

80 - Claims Processing for Special Drug Categories....22

80.1 - Oral Cancer Drugs 22

80.1.1 - HCPCS Service Coding for Oral Cancer Drugs....22

80.1.2 - HCPCS and NDC Reporting for Prodrugs 23

80.1.3 - Other Claims Processing Issues for Oral Cancer Drugs....23

80.1.4 - MSN/ANSI X12 Message Codes for Oral Cancer Drug Denials.23

80.2 - Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen 24

80.2.1 - HCPCS Codes for Oral Anti-Emetic Drugs 25

80.2.2 - Claims Processing Jurisdiction for Oral Anti-Emetic Drugs.....27
80.2.3 - MSN /ANSI X12 Denial Messages for Anti -Emetic Drugs.....29
80.3 - Billing for Immunosuppressive Drugs 29
80.3.1 - Requirements for Billing Intermediary for Immunosuppressive Drugs.....30
80.3.2 - MSN/Remittance Messages for Immunosuppressive Drugs.....31
80.4 - Billing for Hemophilia Clotting Factors.....31
80.5 - Self-Administered Drugs.....32
90 - Claims Processing Rules for Hospital Outpatient Billing and Payment 35
90.1 - Blood/Blood Products and Drugs Classified in Separate APCs for Hospital Outpatients.....35
90.2 - Changes to Pass-Through Drugs and Biologicals Final Rule.....36
90.2.1 - HCPCS Codes Replacements.....36
90.2.2 - Codes Not Recognized for Medicare Under the Hospital OPPS..36
90.2.3 - Additional Drugs Eligible for Pass-Through Payments.....37
90.2.4 - Changes to Payment Rates and Co-Pay from the March 1, 2002 OPPS Final Rule.....38
90.2.5 - Additional Corrections.....38
90.2.6 - Additional Billing and Reporting Information Related to Pass-Through Drugs Effective April 1, 2002.....39
90.2.7 - Typographical Errors from the March 1, 2002 OPPS Final Rule 41
90.2.8 - Correction to 2002 HCPCS Code Books.....41
90.2.9 - Pro-rata Reduction in Drug and Device Pass-Through Payments43

10 - Payment Rules for Drugs and Biologicals

(Rev.)

MCM 3 2049, 5201; PM-A-00-36, PM-B-01-10, PM-B-01-38, PM-AB-01-16

Drugs for inpatient hospital and inpatient SNF beneficiaries are included in the respective PPS rates except for hemophilia clotting factors for hospital inpatients under Part A. These drugs and the codes used to bill for them are listed in Addendum B on the CMS Web site: http://cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf. The Web site is updated as the list of drugs or codes change. HCPCS codes are used by hospitals and SNFS to bill for drugs that are separately billable through September 30, 2002, at which time NDC codes are required by HIPAA. A separate payment may be made for hospital

inpatients, who receive hemophilia clotting factors (but not SNF). See the hospital inpatient billing chapter for instructions on billing inpatient hospital hemophilia clotting factors.

Most drugs furnished to hospital outpatients are packaged under OPPS. Their costs are recognized and included but paid as part of the APC for the service with which they are billed. Certain drugs, however, are paid separately. These include chemotherapeutic agents and the supportive and adjunctive drugs used with them, immunosuppressive drugs, orphan drugs, radiopharmaceuticals, and certain other drugs such as those given in the emergency room for heart attacks.

The classes of drugs required to have "pass through" payments made under BBRA have coinsurance amounts that can be less than 20 percent of the Average Wholesale Price (AWP). This is because pass-through amounts, by law, are not subject to coinsurance. CMS considers the amount of the payment rate that exceeds the estimated acquisition cost of the drug to be the pass-through amount. Thus, the coinsurance is based on a portion of the payment rate, not the full payment rate.

Drugs are billed in multiples of the dosage specified in the HCPCS/NDC. If the dosage given is not a multiple of the HCPCS code, the provider rounds to the next highest units in the HCPCS description for the code.

If the full dosage provided is less than the dosage for the code specifying the minimum dosage for the drug, the provider reports the code for the minimum dosage amount.

Outpatient PPS PRICER includes a table of drugs and prices and provides the intermediary with the appropriate prices.

Section 90 relates specifically to billing for hospital outpatients. The remainder of this chapter relates to procedures for pricing and paying DME recipients, and to beneficiaries who receive drugs under special benefits such as pneumococcal, flu and hepatitis vaccines; clotting factors, immunosuppressive therapy, self administered cancer and anti emetic drugs, and drugs incident to physicians services.

Drugs or biologicals must meet the coverage requirements in Chapter 15, §50 of the Benefit Policy Manual. Additionally, for ESRD patients, see the coverage requirements of Chapter 11, §40 of the Benefit Policy Manual. For ESRD patient billing for drugs and claims processing, see Chapter 8, §50.4, of this manual.

The following chart describes the payment provisions for drugs.

Table - Drug Payment Methodology

References:

MIM 3610.18 (11-01)
MIM 3660.7 (12-00)
MCM 5202.4
PM A 01 93
PM A 01 133
PM A 02 129
Various CMS staff

Provider/Drug	**Hepatitis B Vaccine**	**Pneumococcal & Flu Vaccines**	**Clotting Factors**	**Immuno - Suppressive**	**Erythro-poietin (EPO)**	**Self Admin Anti-Cancer Anti-Emetic**	**Other Drugs**
Hospital Inpatient (IP) A - Prospective Payment System (PPS)	1	1	4	1	1	1	1
Hospital IP A - not PPS	3	3	3	3	3	3	3
Hospital IP B Outpatient Prospective Payment System (OPPS)	5	3	5	5	5	5	5
Hospital IP B - not OPPS hospital	3	3	3	3	3	3	3
Hospital Outpatient (OP) - OPPS hospital	5	3	5	5 *30 day supply	5	5	5

Provider/Drug	Hepatitis B Vaccine	Pneumococcal & Flu Vaccines	Clotting Factors	Immuno - Suppressive	Erythro-poietin (EPO)	Self Admin Anti-Cancer Anti-Emetic	Other Drugs
Hospital OP - not OPPS hospital	3	3	3	3	3	3	5
Skilled Nursing Facility (SNF) IP	1	1	1	1	1	1	1
SNF IP B	3	3	3	3	6	6	6
SNF OP	3	3	3	3	6	6	6
Independent Renal Dialysis Facility (RDF)	3	3	6	6++	7	6	1/2†
Hospital based RDF	5	5	5	6	7	6	3
Comprehensive Outpatient Rehabilitation Facility (CORF)/ Outpatient Rehabilitation Facility (ORF)	5	2	6	2 *	2	6	2
Community Mental Health Clinic (CMHC)	6	6	6	6	6	6	6
Rural Health Clinical (RHC)/Federally Qualified Health Clinic (FQHC) - hospital based	1	1	5	5	5	5	5

Provider/Drug	**Hepatitis B Vaccine**	**Pneumococcal & Flu Vaccines**	**Clotting Factors**	**Immuno - Suppressive**	**Erythro-poietin (EPO)**	**Self Admin Anti-Cancer Anti-Emetic**	**Other Drugs**
RHC/FQHC-independent	1	1	8,2*	8,2*	8,2*	8,2*	8,2*
HHA	5	3	5	5	5	5	5
Hospice	6* 1	6* 1	6* 1	6* 1	6* 1	6* 1	6* 1
Physicians	2*	2 *	2 *	2 *	2 *	2 *	2 *
Pharmacy	2*	2 *	2 *	2 *	7 *	2 *	2 *
Durable Medical Equipment (DME) Supplier	2*	2 *	2 *	2 *	7 *	2 *	2 *
Critical Access Hospital (CAH) Outpt-Method I	3	3	3	3	3	3	3
CAH Outpt-Method II	3	3	3	3	3	3	3
CAH Inpt	3	3	3	3	3	3	3

* Bills carrier or DMERC; no asterisk means bills intermediary or RHHI

† - Drugs & biologicals outside the composite rate are paid as described in 2 below. Those inside the composite rate are paid as described in 1.

1 - Included in PPS rate, or other provider-type all inclusive encounter rate

2 - Lower of 95% AWP or billed charge

3 - Reasonable cost

4 - Lower of cost or 95% AWP paid for drug in addition to PPS rate, or in addition to reasonable cost if excluded from PPS

5 - OPPS-APC, whether pass-thru drug or not

6 - Can not furnish as that "provider" type;

7 - $10.00 per 1000 units (Payment rate for EPO set in statute)

8 - May get carrier billing number if qualified and bill carrier

++ Except in the State of Washington, where we permit the RDF to bill immunosuppressives due to the unique State assistance to the beneficiary provided only via the RDF.

NOTE: RHCs do not bill for vaccines. These are paid on the cost report. Vaccine payment to FQHCs is bundled into the encounter rate.

Hepatitis B vaccine is paid on an APC basis in a hospital outpatient department. Deductible and coinsurance apply.

Influenza and pneumococcal vaccines are also paid on an APC basis in a hospital outpatient department. Neither deductible nor coinsurance apply.

HHAs cannot bill for vaccines, except on TOB 34x, since vaccines are not part of the HH benefit and cannot be paid under HH PPS.

Pneumococcal and influenza are paid once for the vaccine and once for the administration of the vaccine. The provider must enter both HCPCS on separate revenue lines.

20 - Payment Allowance Limit for Drugs and Biologicals

(Rev.)

AB-02-075, AB-02-174, PRM 2711.2 B.2

Title 42 CFR 405.517 specifies that drugs and biologicals not paid on cost or prospective payment basis be paid based on the lower of the actual charge or 95 percent of the national average wholesale price (AWP) as described below.

The table in §10 describes the types of drugs paid by each method.

The CMS establishes a single, national price for intermediary and carrier payment for each Medicare covered drug whose payment allowance is based on 95 percent of the AWP. The four DMERCs jointly establish drug prices for drugs that are billed to DMERCs.

The CMS provides a Single Drug Pricer file to each carrier and intermediary for pricing drugs. Ninety five percent of AWP is to be developed by the carrier only when CMS does not supply a price for the drug. Each intermediary and carrier must accept the Single Drug Pricer files made available by CMS for pricing bills/claims for any drug identified on the price files.

20.1 - Single Drug Pricer (SDP)

(Rev.)

AB-02-174

Effective January 1, 2003, contractors pay drug claims on the basis of the prices shown on the SDP files, if present.

On a quarterly basis, CMS furnishes three SDP files to all FIs, carriers, and ROs except regional home health intermediaries and DMERCs, as follows:

1. "HCPCS" Drug Pricing File

    a. The CMS furnishes a SDP file that contains drugs identified by a code established by the Health Care Procedure Code System (HCPCS). This HCPCS drug pricing file (HDPF) contains:

        - Every HCPCS drug code for every drug for which claims are submitted to local carriers (excluding DMERCs);
        - With respect to each such HCPCS code, the unit of measure by which such HCPCS code is defined;
        - With respect to each HCPCS code and unit of measure, the Medicare

allowed amount;

- With respect to each HCPCS code for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;

- With respect to each new HCPCS code, an indicator to that effect; and

- with respect to each deleted HCPCS code, an indicator to that effect.

b. The filename convention is as follows: (1) "hdpf" in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., hdpf0301.xls).

c. An HDPF will be made available approximately 60 days before the beginning of each calendar quarter, i.e., on or about each February 1st, May 1st, August 1st, and November 1st.

2. "NOC" Drug Pricing File

a. The CMS will furnish a SDP file for drugs NOC. This NOC drug pricing file (NDPF) contains:

- With respect to every drug NOC under the HCPCS for which claims are submitted to local carriers (excluding DMERCs), the NDC code and drug name;

- With respect to each such NDC code, the unit of measure by which such drug is covered;

- With respect to each NOC drug, the Medicare allowed amount;

- With respect to each NOC drug for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;

- With respect to each new NOC drug, an indicator to that effect; and

- With respect to each deleted NOC drug, an indicator to that effect.

b. The filename convention is as follows: (1) "ndpf" in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., ndpf0301.xls).

c. A NDPF will be made available approximately 60 days before the beginning of each calendar quarter, i.e., on or about each February 1st, May 1st, August 1st, and November 1st.

NOTE TO FIs: The NOC file does not necessarily contain all NOC drugs. Intermediaries must contact local carriers to determine if there are other drugs they have priced separately and request the prices for those drugs if needed.

3. The CMS will furnish a pricing documentation file (PDF) that contains:

    a. The data in the drug pricing file, i.e., each HCPCS code and its Medicare allowed amount;

    b. With respect to each HCPCS drug code, every product, as identified by its NDC code, that contains the same active ingredient as specified in the definition of the HCPCS code;

    c. With respect to those NDC codes used to determine the Medicare-allowed amount, an indicator to that effect;

    d. With respect to each such NDC, the price or prices used to determine the average wholesale price (AWP) of the product;

    e. With respect to each such price, an identification of the source(s) of the price; and

    f. With respect to each such source, the date, edition, and other information necessary and sufficient to enable CMS to verify the price.

Upon receiving the quarterly update files, contractors must execute their normal update process using the SDP files. They must process manually if necessary to implement SDP files' prices effective with the beginning of the following quarter. and compare the prices paid previously with the prices shown on the prior SDP file. Contractors must take note of the unit pricing quantity shown on the applicable SDP file and compare it to the unit pricing quantity to ensure that any apparent price changes are real. Carriers must notify physicians of price changes. Intermediaries must notify ESRD facilities (with respect to ESRD drugs not included in the composite rate) and hospitals (with respect to clotting factors) of price changes to the extent and in the manner you have done previously. Any price on a SDP file that is believed to be erroneous should be brought to the attention of the CMS RO.

Contractors may not substitute their price for the price shown on an SDP file unless authorized to do so by a joint memorandum from CMS.

If updated prices, in whole or in part, are not made available on a timely basis, contractors must use the prices from the prior quarter's SDP files to the extent necessary.

Carriers continue to price drugs as outlined in §20.2 with respect to any drug that is not listed on the SDP files and with respect to any compounded drug that is not identified by a single National Drug Code (NDC). On or before March 1st of each year, they must report to the RO whether any drugs are being priced separately, including but not limited to NOC drugs. If one or more drugs are being priced separately, then the name of the drug, its NDC, the price determined, and the source used to price drug must also be

included in the report.

Intermediaries must as needed on a quarterly basis and within seven days of receipt of the SDP files, request from carriers prices of drugs that they may price separately. Carriers upon request, on a quarterly basis and within seven days of any such request, furnish to intermediaries within jurisdiction, free of charge, the subset of files, which includes drugs that are priced separately.

Contractors must respond to questions about price changes and the implementation of AWP pricing as done previously. Contractors respond to questions about the SDP on the basis of these instructions. Questions that cannot be answered should be referred to the RO.

ROs will:

1. Advise carriers concerning the implementation of the SDP.

2. Respond to questions about drug price changes as done previously.

3. Respond to questions about the implementation of the AWP pricing methodology as done previously.

4. Respond to questions about the SDP on the basis of these instructions.

5. Refer any questions that cannot be answered to central office (CO) per item 6, below.

6. Advise CO of matters that require CO attention**.**

20.2 - Calculation of the AWP

(Rev.)

AB-02-075, PRM 2711.2 B.2

Carriers must ensure that if any NDCs are added or deleted, the formulae are applied appropriately.

A separate AWP is calculated for each drug as defined by a HCPCS code. Within each HCPCS code there may be a single source or there may be many sources.

- For a single-source drug or biological, the AWP equals the AWP of the single product.

- For a multi-source drug or biological, the AWP is equal to the lesser of;

    - The median AWP of all generic forms of the drug or biological; or

    - The lowest brand name product AWP.

A "brand name" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological.

Note: Repackagers make the status of the drug a multi-source.

After determining the [median] AWP [and the lowest brand name price], carriers multiply the lower of the two by 0.95 and round to the nearest penny. This is the drug payment allowance limit. There is no minimum for this amount.

Intermediaries get drug prices from the carrier for drugs not listed on the Single Drug Pricer.

20.3 - Detailed Procedures for Determining AWPs and the Drug Payment Allowance Limits

(Rev.)

AB-02-075, PRM 2711.2 B. 2

20.3.1 - Background

(Rev.)

Payment for drugs and biologicals under Medicare is determined by a standard methodology. Law and regulations require that a drug payment allowance limit be used as described in §20.1. (See 42 CFR 405.517).

Drug payment allowance limits are updated no less than quarterly. Quarterly updates are in response to additions and deletions of codes received from CMS through HCPCS updates, and in response to price changes reported to carriers' sources by manufacturers and labelers. (New drugs, which are approved by FDA, may be added at any time.)

When limits are updated, carriers inform intermediaries and the provider community as described in paragraph §30 below.

20.3.2 - Review of Sources for Medicare Covered Drugs and Biologicals

(Rev.)

Carriers check updates for Medicare covered services or procedures for new codes or code description changes before updating files.

For new codes, the Carrier Medical Staff determines coverage in accordance with the coverage rules in Chapter 15, §50, of the Medicare Benefits Policy Manual.

Carriers refer to common sources for drug pricing information. Examples are the various Redbook products, "Drug Facts and Comparisons", the FDA publication Approved Drug Products with Therapeutic Equivalence (the Orange Book), or the "Hospital Formulary

Pricing guide by MediSpan, Inc." If a price cannot be located in the available sources, they contact the manufacturer of the drug.

If a code has a description change, carriers adjust formulas to account for any changes in the strength or dosage of the drug. For example, if a code is listed as 50 mg, and changed to100 mg. the drug payment allowance limit is adjusted to compensate for the difference in the dosage.

20.3.3 - Use of Generics

(Rev.)

Carriers identify the generic name of the drug from the code description. They always rely on the CMS HCPCS tape file or an official HCPCS publication.

Carriers locate generic sources in the Drug Topics Redbook or other source based on the HCPCS description of the drug. They use entries that match the strength of the drug described by the HCPCS code, e.g. 50 mg, 100 mg, etc.

To determine if a drug is generic or brand, carriers compare the name of the drug in the HCPCS code (generic) with the name of the drug being identified. If they are the same, the drug is generic. If they are different, the drug is a brand. For example, the description for J3360 is injection, diazepam, up to 5 mg. Diazepam is the generic name. The HCPCS code for Valium is listed as J3360. Valium is a brand name.

If there is a question as to whether a drug is brand or generic, carriers consult the PDR Generics, or telephone the drug company.

20.3.4 - Find the Strength and Dosage

(Rev.)

Carriers use ampules, single dose and multiple dose vials and repacks to compare the strength and dosage. If multiple dose vials are used, carriers must determine how they are used, based on the strength indicator compared with the HCPCS code description (i.e., if the strength on the vial matches the HCPCS description, multi-dose vials should be used).

Carriers must determine which of the following conditions are true before pricing the drug:

1. The strength and dosage of the drugs in the price source match the HCPCS code and description.

   Carriers calculate allowable reimbursements for drugs using "all" the NDCs for a given active drug ingredient and calculate a unit price that is associated with the HCPCS descriptor. If, for example, the HCPCS code descriptor specifies 50 ml and there is a 50 ml size shown in the Redbook or other source material, they may use only the 50 ml size (and not use 10-5 ml vials) or may use all products that

meet the strength based on strength and volume of the drug. In the latter case price per unit is calculated and then converted to the HCPCS units definition.

2. The strength and dosage from the HCPCS code description are not found in the price source.

   Carriers use the closest dosage to the HCPCS definition without exceeding the dosage.

3. The strength and dosage in the price source do not include a generic form but do include a brand form.

   Carriers use the lowest brand price.

20.3.5 - Restrictions

(Rev.)

To determine AWPs and Payment Allowance Limits, carriers:

- Exclude special sized packaging, e.g. Institutional Use.
- Do not use flip top vial, carpu-ject, tubes, cartridge, rapi-ject, lure lock syringe, blunt point abu-ject, rapi-ject, leurlock, advantage, min-i-jet, unless it's the only source available. These items are considered convenience and tend to inflate the price.
- Do not use drugs marked preservative free, sulfite free, piggy back or sterile unless the HCPCS description specifies otherwise.
- Do not use drugs with an Orange Book Code (OBC) other than "A" if more than one source exists. This restriction applies to SADMERC only (reference CMS Memorandum PUB 60 AB.94-2, 60 dated 3/94*).*

20.3.6 - Inherent Reasonableness for Drugs and Biologicals

(Rev.)

AB-02-075, PRM 2711.2 B. 2

Section 4316 of the Balanced Budget Act of 1997 permits Medicare carriers to establish realistic and equitable payment amounts for drugs when the existing payment amounts are inherently unreasonable because they are either grossly excessive or deficient. Refer to the Medicare Claims Processing Manual, Chapter 23, "Coding Requirements and Fee Schedules," §90, for a complete description of Inherent Reasonableness rules.

Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to the following:

1. Payment amounts for drugs or biologicals are grossly higher or lower than acquisition or production costs for the category of items or services.

2. There have been increases in payment amounts that cannot be explained by inflation or technology.

In some instances, the calculation of the AWP may lead to a payment limit that is not reasonable for the purpose of paying for drugs and biologicals. Carriers can apply the principal of inherent reasonableness in selecting the drugs to be included in the calculation. For instance in situations where there are some drugs in a HCPCS grouping that are significantly more expensive due to having preservatives added, there is no effect on the quality of the drug whether or not there are preservatives. Therefore, leave the drugs with preservatives out of the calculation.

While carriers and intermediaries may determine under their inherent reasonableness authority that a greater than 15 percent increase or decrease in payment amounts is warranted, they may not increase or decrease the payment amounts for any item by greater than 15 percent in any given year. However, a contractor may determine that a 25 percent reduction is warranted, and accomplish the adjustment over 2 years, e.g., 15 percent applied the first year, and 10 percent applied the following year.

In addition, a contractor must inform CMS of any inherent reasonableness determinations. CMS will then acknowledge receipt of the notification. The payment adjustment may not take effect until the contractor has notified CMS and received CMS's acknowledgment of the notification.

Notification should be sent to CMS Central Office (CO) at the following address:

Centers for Medicare & Medicaid Services
Center for Medicare Management
Provider Billing Group
C4-10-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

30 - Carrier Distribution of Limit Amounts

(Rev.)

Intermediaries get drug prices from the carrier for drugs not listed on the Single Drug Pricer.

Carriers prepare a list of the drug payment allowance limits updates (or new file depending upon local requirements) to the claims system.

Carriers distribute, free of charge, the updated limits in an agreed upon format directly to the fiscal intermediaries in their jurisdiction.

Carriers should contact the fiscal intermediaries to determine the preferred method of transmission. Carriers are to send this information to all fiscal intermediaries they routinely deal with. If this method of obtaining payment allowance updates does not work for any intermediary, the carrier must contact the appropriate regional office.

Each carrier publishes the drug payment allowance limits on its Web site and/or in a provider bulletin at least 30 days prior to implementation.

40 - Discarded Drugs and Biologicals

(Rev.)

AB-02-075, PRM 2711.2 B. 2

CMS encourages physicians to schedule patients in such a way that they can use drugs most efficiently. However, if a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered.

NOTE: The coverage of discarded drugs applies only to single use vials. Multi-use vials are not subject to payment for discarded amounts of drug.

EXAMPLE 1

A physician schedules three Medicare patients to receive Botulinum Toxin Type A on the same day within the designated shelf life of the product. Currently, Botox is available only in a 100-unit size. Once Botox is reconstituted in the physician's office, it has a shelf life of only 4 hours. Often, a patient receives less than a 100 unit dose. The physician administers 30 units to each patient. The remaining 10 units are billed to Medicare on the account of the last patient. Therefore, 30 units are billed on behalf of the first patient seen and 30 units are billed on behalf of the second patient seen. Forty units are billed on behalf of the last patient seen because the physician had to discard 10 units at that point.

EXAMPLE 2

A physician must administer 15 units of Botulinum Toxin Type A to a Medicare patient, and it is not practical to schedule another patient who requires Botulinum Toxin. For example, the physician has only one patient who requires Botulinum Toxin, or when the physician sees the patient for the first time and did not know the patient's condition. The physician bills for 100 units on behalf of the patient and Medicare pays for 100 units.

50 - Assignment Required for Drugs and Biologicals

(Rev.)

PM B-01-15

A - Local Carriers

Under §114 of the Benefits Improvement Act of 2000, payment for any drug or biological covered under Part B of Medicare may be made only on an assignment-related basis. Therefore, no charge or bill may be rendered to beneficiaries for these drugs and biologicals for any amount except for any applicable unmet Medicare Part B deductible and coinsurance amounts.

Mandatory assignment does not apply to Healthcare Common Procedure Coding System (HCPCS) code E0590, which represents the dispensing fee for nebulizer drugs.

Carriers process all claims for drugs and biologicals with a date of service on or after February 1, 2001 as though the physician or non-physician practitioner had taken assignment. If only drugs and biologicals are billed on the claim, and the claim was submitted as unassigned, contractors change the claim to assigned and process as an assigned claim. If a physician or non-physician practitioner submits an unassigned claim that contains both codes for drugs or biologicals and codes for other services, carriers split the claim into two claims. The first claim will be an unassigned claim for services other than drugs or biologicals, and the second will be an assigned claim for drugs or biologicals furnished on or after February 1, 2001. The following messages apply when a carrier has changed the claim to assigned status (regardless of whether the contractor had to split the claim):

- Remittance advice remark code N71, "Your unassigned claim for a drug or biological, clinical diagnostic laboratory services or ambulance service was processed as an assigned claim. You are required by law to accept assignment for these types of claims."

- MSN 16.50 English, "The doctor or supplier may not bill more than the Medicare approved amount," **or** MSN 16.50 Spanish, "El doctor o suplidor no podrá facturar más que la cantidad aprobada por Medicare."

- Remark Code MA 72, "The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between his/her payment to you and the total amount shown as patient responsibility and as paid to the beneficiary on this notice."

Additional appropriate message for physicians, suppliers and beneficiaries should be added as necessary.

B - DMERCs

Under §114 of BIPA, DMEPOS suppliers must accept assignment on all claims for drugs and biologicals that they bill to the DMERCs. A supplier may not render a charge or bill to anyone for these drugs and biologicals for any amount other than the Medicare Part B deductible and coinsurance amounts.

Mandatory assignment does not apply to CMS Common Procedure Coding System (HCPCS) code E0590, which represents the dispensing fee for nebulizer drugs.

DMERCs must inform suppliers on their Web sites and in their next bulletins that they must accept assignment on claims for drugs and biologicals furnished on or after February 1, 2001.

DMERCs must deny any claims a beneficiary submits for drugs and biologicals with dates of service on or after February 1, 2001. The DMERCs must notify beneficiaries that suppliers are now required to accept assignment on claims for drugs and biologicals, and therefore, the beneficiaries may not submit claims for drugs and biologicals themselves. When denying beneficiary-submitted claims, use the following Medicare Summary Notice (MSN) messages:

> MSN 16.6 (English): "This item or service cannot be paid unless the provider accepts assignment."
>
> MSN 16.6 (Spanish): "Este artículo o servicio no se pagará a menos de que el proveedor acepte asignación."
>
> MSN 16.7 (English): "Your provider must complete and submit your claim."
>
> MSN 16.7 (Spanish): "Su proveedor debe completar y someter su reclamación."
>
> MSN 16.34 (English): "You should not be billed for this service. You do not have to pay this amount."
>
> MSN 16.34 (Spanish): "Usted no debería ser facturado por este servicio. Usted no tiene que pagar esta cantidad."
>
> MSN 16.36 (English): "If you have already paid it, you are entitled to a refund from this provider."
>
> MSN 16.36 (Spanish): "Si usted ya lo ha pagado, tiene derecho a un reembolso de su proveedor."

If a supplier submits an unassigned claim with a date of service on or after February 1, 2001, to the DMERC for a drug or biological, the DMERC must process the claim as though the supplier accepted assignment. It is possible that a supplier may bill drugs and other items on the same claim, which would result in a claim with some assigned and some non-assigned items.

In the event that a supplier bills an unassigned claim to a DMERC that contains both codes for drugs or biologicals and codes for other items, the DMERCs must replicate the claim. This will result in two claims in the DMERC system: an unassigned claim for items other than drugs or biologicals, and an assigned claim for drugs and biologicals furnished on or after February 1, 2001. When a DMERC changes an unassigned drug claim to an assigned claim, they must use the following messages on the supplier remittance advice:

> Remark code MA72: "The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between his/her payment to you and the total of the amount shown as patient responsibility and as paid to the beneficiary on this notice." (VMS shared system maintainer must use remark code MA72 on the claim level on the remittance advice for drugs and biologicals when the incoming claim indicated that the patient had already paid for the billed services.)
>
> Remark code N71: "Your unassigned claim for a drug or biological was processed as an assigned claim. The law requires that you must take assignment on all claims for drugs and biologicals."

The VMS Shared System Maintainer must hard-code remittance message MA72 and remittance message N71 into their system.

All suppliers who bill the DMERCs for drugs for use with DMEPOS must have a pharmacy license to dispense drugs. When a DMERC denies a claim for a drug because the NSC's records do not show that the supplier has a pharmacy license, the DMERC must also deny any equipment, accessories, and supplies related to the drug, when the supplier bills the drug on the same claim as the equipment. (Suppliers should bill drugs for use with DMEPOS on the same claim as the equipment itself, if they are also providing and billing for the equipment.) In situations when a supplier bills unassigned drugs and equipment, accessories, or supplies on the same claim, the DMERC and VMS Shared System Maintainer must ensure that they apply non-licensed pharmacy equipment, accessory and supply edits and denials before they replicate the claim. Even if the system denies a line due to the nonlicensed pharmacy edit prior to replicating the claim, the system must still replicate any unassigned claims for drugs and biologicals and change the assignment indicator. DMERCs use the following messages to suppliers, as appropriate:

> Remittance advice MA72: "The beneficiary overpaid you for these assigned services. You must issue the beneficiary a refund within 30 days for the difference between his/her payment to you and the total of the amount shown as patient responsibility and as paid to the beneficiary on this notice." (VMS shared system maintainer must use remark code MA72 on the claim level on the remittance advice for drugs and biologicals when the incoming claim indicated that the patient had already paid for the billed services.)

Remark code N71: "Your unassigned claim for a drug or biological was processed as an assigned claim. The law requires that you must take assignment on all claims for drugs and biologicals."

Adjustment reason code B6: "This service/procedure is denied/reduced when performed/billed by this type of provider, by this type of provider in this type of facility, or by a provider of this specialty."

Adjustment reason code #107: "Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim."

Remark code M143: "We have no record that you are licensed to dispense drugs by the state in which you are located."

The DMERCs must work together to create and maintain a list of HCPCS drug codes which suppliers must bill on an assigned basis. This will enable VMS shared system maintainer and the DMERCs to implement the necessary edits in their systems. Finally, the four DMERCs must work together to create a list of drug and equipment codes to which the non-licensed pharmacy edit would apply in this situation. For this second list, the DMERCs need only add drugs that are used with equipment, and the equipment, and related supplies and accessories, that use those drugs, as opposed to all drugs that are subjected to the licensure edit. The DMERCs must share these lists with VMS shared system maintainer and CMS Central Office.

60 - License Required to Dispense Drugs

(Rev.)

PM B-01-02

Regulations at 42 CFR 424.57(b)(4) (supplier standards) state that a "supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs. (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.)"

Therefore, suppliers may not bill the Durable Medical Equipment Regional Carriers (DMERCs) for any Medicare-covered drugs unless they have a State license to dispense the drugs, regardless of whether or not the drugs require a prescription. Similarly, a physician may not dispense Medicare-covered prescription or nonprescription drugs unless he or she is authorized by the State to dispense such drugs as part of his or her physician's license.

DMERCs must deny claims for prescription drugs, and related equipment when billed on the same claim, if the National Supplier Clearinghouse's (NSC) records show the supplier was not licensed to dispense the drug on the DOS (date of service).

In effect, for DOS on or after December 11, 2000, the DMERCs must deny claims for all Medicare- covered drugs dispensed by a supplier or physician who is not licensed to dispense the drug. If the DMERCs feel that it is necessary, they may coordinate to develop a list of drugs and related equipment that should be subjected to the licensure edit.

Note that these provisions do not apply to EPO. Method I beneficiaries must obtain their EPO through their dialysis facilities, and Method II beneficiaries must receive EPO from the same supplier that provides all their other dialysis supplies.

70 - Claims Processing Requirements - General

(Rev.)

No Xref-Staff developed

Carriers are billed with the Form CMS-1500 data set and intermediaries with the Form CMS-1450 data set (paper or approved EDI data set).

See chapters 25 and 26 for detailed claims processing requirements, including forms, data elements, and formats; and chapters 21 and 22 for MSN and remittance record requirements.

In addition to requirements applicable to all claims the following apply to drug claims.

- On claims to intermediaries the drug is identified by the appropriate HCPCS code for the drug administered and billed under revenue code 636 unless specific instruction states otherwise;

- On claims to carriers the drug is identified by HCPCS code;

- All drugs, including Prodrugs, are reported to DMERCS by National Drug Code (see §80.1.2);

- Where HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;

- Where the NDC is required units are entered in multiples of the units shown in the NDC label description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;

- If the units provided exceeds the size of the units field, e.g., requires over three characters to report, repeat the HCPCS or NDC code on multiple lines until all units can be reported;

- Covered administration codes for injections may be billed to the carrier and intermediary in addition to billing for the drug. The drug maximum payment

allowance is for the drug alone. However, if payment is under a PPS, such as OPPS, the injection would be included in the APC rate.

See §10 for a description of drug payment rules.

80 - Claims Processing for Special Drug Categories

(Rev.)

NOTE: Preventive vaccines, influenza, pneumococcal and hepatitis B, are covered in Chapter 18 of this manual.

NOTE: The definition of Off-Label and its uses are described in the Medicare Benefit Policy Manual, Chapter 15, §50.4, and its subsections.

80.1 - Oral Cancer Drugs

(Rev.)

A3 3660.13, SNF 536.1

Effective January 1, 1994, oral self administered versions of covered injectable cancer drugs furnished may be paid if other coverage requirements are met. To be covered the drug must have had the same active ingredient as the injectable drug. Effective January 1, 1999, this coverage was expanded to include FDA approved Prodrugs used as anti-cancer drugs. A Prodrug may have a different chemical composition than the injectable drug but body metabolizing of the Prodrug results in the same chemical composition in the body.

80.1.1 - HCPCS Service Coding for Oral Cancer Drugs

(Rev.)

The following codes may be used for drugs other than Prodrugs, when covered:

Generic/Chemical Name	How Supplied	HCPCS
Busulfan	2 mg/ORAL	J8510
Capecitabine	150mg/ORAL	J8520
Capecitabine	500mg/ORAL	J8521
Methotrexate	2.5 mg/ORAL	J8610
Cyclophosphamide *	25 mg/ORAL	J8530
Cyclophosphamide *	50 mg/ORAL	J8530

Generic/Chemical Name	How Supplied	HCPCS
(Treat 50 mg. as 2 units		
Etoposide	50 mg/ORAL	J8560
Melphalan	2 mg/ORAL	J8600
Prescription Drug chemotherapeutic NOC	ORAL	J8999

Each tablet or capsule is equal to one unit, except for 50 mg./ORAL of cyclophosphamide (J8530), which is shown as 2 units. The 25m and 50 mg share the same code.

Note: HIPAA requires that drug claims submitted to DMERCs be identified by National Drug Code (NDC).

80.1.2 - HCPCS and NDC Reporting for Prodrugs

(Rev.)

Intermediary claims

For oral anti-cancer Prodrugs HCPCS code J8999 is reported with revenue code 636.

DMERC claims

The supplier reports the NDC code on the claim. The DMERC converts the NDC code to a 'WW' HCPCS code for CWF.

80.1.3 - Other Claims Processing Issues for Oral Cancer Drugs

(Rev.)

Deductible and coinsurance apply.

A cancer diagnosis code must be reported when billing for these HCPCS codes. If there is no cancer diagnosis the claims is denied.

The number of tablets or capsules is reported as units.

80.1.4 - MSN/ANSI X12 Message Codes for Oral Cancer Drug Denials

(Rev.)

If the claim for an oral cancer drug is denied because it was not approved by FDA, is not considered to be a medically accepted treatment for cancer, or is not the chemical

equivalent of a covered injectable cancer drug (or a covered Prodrug), use the appropriate message on the MSN:

> 6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (ANSI X12 Adjustment Code 114)
>
> 6.3 - Payment cannot be made for oral drugs that do not have the same active ingredients as they would have if given by injection. (ANSI X12 Group Code-PR 46)

80.2 - Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen

(Rev.)

B3-4460, A3-3660.15, PM A-98-5

See Chapter 15, §50.5.4, of the Medicare Benefits Policy Manual for detailed coverage requirements.

Effective for dates of service on or after January 1, 1998, intermediaries and carriers pay for oral anti-emetic drugs when used as full therapeutic replacement for intravenous dosage forms as part of a cancer chemotherapeutic regimen when the drug(s) is administered or prescribed by a physician for use immediately before, at, or within 48 hours after the time of administration of the chemotherapeutic agent.

The allowable period of covered therapy includes day one, the date of service of the chemotherapy drug (beginning of the time of treatment), plus a period not to exceed two additional calendar days, or a maximum period up to 48 hours. Some drugs are limited to 24 hours; some to 48 hours. The hour limit is included in the narrative description of the HCPCS code.

The oral anti-emetic drug(s) should be prescribed only on a per chemotherapy treatment basis. For example, only enough of the oral anti-emetic(s) for one 24 or 48 hour dosage regimen (depending upon the drug) should be prescribed/supplied for each incidence of chemotherapy treatment. These drugs may be supplied by the physician in the office, by an inpatient or outpatient provider (e.g., hospital, CAH, SNF, etc.), or through a supplier (e.g., a pharmacy).

The physician must indicate on the prescription that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen. Where the drug is provided by a facility, the beneficiary's medical record maintained by the facility must be documented to reflect that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.

Payment for these drugs is made under Part B. Payment is based on the lower of the actual charge on the Medicare claim or 95 percent of the lesser of the median average wholesale price for all sources of the generic forms of the drug or lowest priced brand name product. Deductible and coinsurance apply

HCPCS codes shown in §80.2.1 are used.

Common Working File edits claims with these codes to assure that the beneficiary is receiving the oral anti-emetic(s) as part of a cancer chemotherapeutic regimen by requiring a diagnosis of cancer.

Most drugs furnished as an outpatient hospital service are packaged under OPPS. However, chemotherapeutic agents and the supportive and adjunctive drugs used with them are paid separately.

80.2.1 - HCPCS Codes for Oral Anti-Emetic Drugs

(Rev.)

The physician/supplier bills for these drugs on Form CMS-1500 or its electronic equivalent. The facility bills for these drugs on Form CMS-1450 or its electronic equivalent. The following HCPCS codes are assigned:

Q0163 DIPHENHYDRAMINE HYDROCHLORIDE 50mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at time of chemotherapy treatment not to exceed a 48 hour dosage regimen.

Q0164 PROCHLORPERAZINE MALEATE 5mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0165 PROCHLORPERAZINE MALEATE 10mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0166 GRANISETRON HYDROCHLORIDE 1mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24 hour dosage regimen.

Q0167 DRONABINOL 2.5mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0168 DRONABINOL 5mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0169 PROMETHAZINE HYDROCHLORIDE 12.5mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0170 PROMETHAZINE HYDROCHLORIDE 25mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0171 CHLORPROMAZINE HYDROCHLORIDE 10mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0172 CHLORPROMAZINE HYDROCHLORIDE 25mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0173 TRIMETHOBENZAMIDE HYDROCHLORIDE 250mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0174 THIETHYLPERAZINE MALEATE 10mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0175 PERPHENAZINE 4mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0176 PERPHENAZINE 8mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hours dosage regimen.

Q0177 HYDROXYZINE PAMOATE 25mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0178 HYDROXYZINE PAMOATE 50mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0179 ONDANSETRON HYDROCHLORIDE 8mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen.

Q0180 DOLASETRON MESYLATE 100mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24 hour dosage regimen.

Q0181 UNSPECIFIED ORAL DOSAGE FORM, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

NOTE: The 24 hour maximum drug supply limitation on dispensing, for HCPCS Codes Q0166 and Q0180, has been established to bring the Medicare benefit as it applies to these two therapeutic entities in conformity with the "Indications and Usage" section of currently FDA approved product labeling for each affected drug product.

80.2.2 - Claims Processing Jurisdiction for Oral Anti-Emetic Drugs

(Rev.)

The table in §10 shows intermediary/carrier jurisdiction for oral anti-emetic drugs. The entity identified by asterisk * is either carrier or DMERC jurisdiction. Within this, the following chart shows which drugs are billed to the local carrier and which to the DMERC. (NDC in the chart means National Drug Code.)

Per the BBA '97, effective for claims with dates of service on or after January 1, 1998, the claims processing jurisdiction rules in Chart 1 apply.

CHART 1

COMBINATION	JURISDICTION
Oral chemotherapy drug with oral anti-emetic drug	DMERC maintains processing responsibility for the NDC oral chemotherapy drug and the K0415 oral anti-emetic drug code combinations. DMERC processes the NDC oral chemotherapy drug and Q code oral anti-emetic drug(s) when provided in the physician's office. DMERC processes the NDC oral chemotherapy drug and/or Q code oral anti-emetic drug(s) when supplied by a pharmacy.
Oral chemotherapy drug with rectal anti-emetic drug	DMERC maintains responsibility for processing both the NDC oral chemotherapy drug and the K0416 rectal anti-emetic drug.
Oral chemotherapy drug with intravenous anti-emetic drug	DMERC maintains responsibility for processing the NDC oral chemotherapy drug and the local carrier for processing the intravenous anti-emetic J code drug(s).

COMBINATION	JURISDICTION
Intravenous chemotherapy drug with oral anti-emetic drug	Local carrier processes the intravenous J code chemotherapy drug. The oral anti-emetic Q code drug(s) is processed by the DMERC when provided in the physician's office or when provided by a supplier.
Intravenous chemotherapy drug with intravenous anti-emetic drug	Local carrier processes both intravenous chemotherapy J code drug and intravenous anti-emetic J code drug(s).

For claims with dates of service prior to January 1, 1998, per OBRA '93, the claims processing jurisdiction rules in Chart 2 apply.

CHART 2

COMBINATION	UNDER OBRA '93
Oral chemotherapy drug with oral anti-emetic drug	DMERC processes both chemotherapy drug (NDC) [1] and the anti-emetic drug (K0415 code) [2].
Oral chemotherapy drug with rectal anti-emetic drug	DMERC processes both the chemotherapy drug (NDC) [1] and the anti-emetic drug (K0416 code) [2].
Oral chemotherapy drug with intravenous anti-emetic drug	DMERC processes the oral chemotherapy drug (NDC) [1] and the local carrier processes the intravenous anti-emetic drug (NDC) [3].
Intravenous chemotherapy drug with oral anti-emetic drug	Local carrier processes intravenous chemotherapy drug (NDC) [3] and self-administered oral anti-emetic drug is noncovered.
Intravenous chemotherapy drug with intravenous anti-emetic drug	Local carrier processes both intravenous chemotherapy drug (NDC) [3] and intravenous anti-emetic drug (NDC) [3].

Key: 1 = OBRA '93 Legislation (Coverage for Oral Anti-Cancer Drugs)

2 = Carrier Manual Transmittal No. 1528 (November 1995) (Adds oral/rectal anti-emetic)

3 = "Incident to" a physician service

Providers (HIPAA definition) that bill the DMERC will require a supplier number issued by the National Supplier Clearinghouse (NSC) in order to submit claims . Medicare Part

B carriers should instruct providers without a supplier number to contact the NSC service center at 803-754-3951 to request an enrollment package for a supplier number.

80.2.3 - MSN /ANSI X12 Denial Messages for Anti-Emetic Drugs

(Rev.)

If the claim for an oral cancer drug is denied because it was not approved by FDA, is not considered to be a medically accepted treatment for cancer, or is not the chemical equivalent of a covered injectable cancer drug (or a covered Prodrug), use the appropriate message on the MSN:

6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (ANSI X12 Adjustment Code 114)

6.3 - Payment cannot be made for oral drugs that do not have the same active ingredients as they would have if given by injection. (ANSI X12 Group Code-PR 46)

6.4 - Medicare does not pay for an oral anti-emetic drug that is not administered for use immediately before, at, or within 48 hours after administration of a Medicare covered chemotherapy drug. (ANSI X12 Group Code PR 96 with Remark Code M100)

80.3 - Billing for Immunosuppressive Drugs

(Rev.)

B3-4471, A3-3660.8, PM AB-01-10

Beginning January 1, 1987, Medicare pays for FDA approved immunosuppressive drugs and for drugs used in immunosuppressive therapy. (See Medicare Benefit Policy Manual, Chapter 15, §50.5.1, of for detailed coverage requirements.) Generally, contractors pay for self-administered immunosuppressive drugs that are specifically labeled and approved for marketing as such by the FDA, or identified in FDA-approved labeling for use in conjunction with immunosuppressive drug therapy. This benefit is subject to the Part B deductible and coinsurance provision.

Contractors are expected to keep informed of FDA additions to the list of the immunosuppressive drugs and notify providers. Prescriptions for immunosuppressive drugs generally should be nonrefillable and limited to a 30-day supply. The 30-day guideline is necessary because dosage frequently diminishes over a period of time, and further, it is not uncommon for the physician to change the prescription from one drug to another. Also, these drugs are expensive and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, contractors will not consider a supply of drugs in excess of 30 days to be reasonable and necessary and should deny payment accordingly.

Entities that normally bill the carrier bill the DMERC. Entities that normally bill the intermediary bill the intermediary, except for hospitals subject to OPPS, which must bill the DMERC.

Prior to December 21, 2000 coverage was limited to immunosuppressive drugs received within 36 months of a transplant. ESRD beneficiaries continue to be limited to 36 months of coverage after a Medicare covered kidney transplant. For all other beneficiaries, BBA '97 increased the length of time a beneficiary could receive immunosuppressives by a sliding method. So for the period 8/97 thru 12/00 a longer period of time MAY apply for a transplant. Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no time limit, but an organ transplant must have occurred for which immunosuppressive therapy is appropriate. That is, the time limit for immunosuppressive drugs was eliminated for transplant beneficiaries that will continue Medicare coverage after 36 months based on disability or age. The date of transplant is reported to the intermediary with occurrence code 36.

CWF will edit claim records to determine if a history of a transplant is on record. If not an error will be returned. See Chapter 27, CWF Resolution Procedures for edit codes and resolution.

80.3.1 - Requirements for Billing Intermediary for Immunosuppressive Drugs

(Rev.)

Hospitals not subject to OPPS bill on a Form CMS-1450 with bill type 12x (hospital inpatient Part B) or l3x (hospital outpatient) as appropriate. For claims with dates of service prior to April 1, 2000, providers report the following entries:

- Occurrence code 36 and date in FL 32-35;
- Revenue code 250 in FL 42; and
- Narrative description in FL 43.

For claims with dates of service on or after April 1. 2000, hospitals report

- Occurrence code 36 and date in FL 32-35;
- Revenue code 636 in FL 42;
- HCPCS code of the immunosuppressive drug in FL 44; and
- Number of units in FL 46 (the number of units billed must accurately reflect the definition of one unit of service in each code narrative. E.g.: If fifty 10-mg. Prednisone tablets are dispensed, the hospital bills J7506, 100 units (1 unit of J7506 = 5 mg.).

The hospital completes the remaining items in accordance with regular billing instructions.

80.3.2 - MSN/Remittance Messages for Immunosuppressive Drugs

(Rev.)

A - MSN

MSN messages for denied Immunosuppressive Drugs are as follows:

If no transplant use:

> 6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered.

If the claim for an immunosuppressive drug is partially denied because of the 30-day supply limitation, use the following message:

> 4.3 - Prescriptions for immunosuppressive drugs are limited to a 30-day supply.

B - Remittance

Remittance codes/messages for denied Immunosuppressive Drugs are as follows:

If the claim is denied because the immunosuppressive drug is not approved by the FDA, the intermediary uses existing American National Standard Institute (ANSI) X-12-835 claim adjustment reason code/message 114, Procedure/product not approved by the Food and Drug Administration.

If the claim is denied because the benefit period has expired or because of the 30 day limitation, the intermediary uses existing ANSI X-12-835 claim adjustment reason code/message 35, Benefit maximum has been reached.

If the claim is denied for the immunosuppressive drug because a transplant was not covered, the intermediary uses existing ANSI X-12-835 claim adjustment reason code/message 107, Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

80.4 - Billing for Hemophilia Clotting Factors

(Rev.)

B3-5245, PM AB-00-117

See the table in §10 of this chapter for claims jurisdiction and payment method. Carriers pay claims from suppliers such as independent pharmacies, Red Cross, durable medical

equipment supplier, independent blood bank, and independent hemophilia centers. Hospital based hemophilia centers are considered hospitals for claims jurisdiction.

Where the drug is priced either using AWP or under OPPS, any related supplies that are covered, such as syringes, are paid by the DMERC based on the DME fee schedule. If the clotting factor is dispensed by a hospital subject to OPPS, the related supplies are either packaged with the drug or paid based on the DMEPOS fee schedule. Covered related supplies are only paid by the DMERC if the clotting factors are given to the beneficiary to be self-administered. Related supplies for inpatients are considered part of operating costs and are considered included in the PPS rate or are paid based on a reasonable cost basis, depending upon the general payment rules applicable to the provider.

Reimbursement is based upon the least expensive medically necessary blood clotting factors. Blood clotting factors are available both in virally inactivated forms and a recombinant form. The Food and Drug Administration (FDA) has determined that both varieties are safe and effective. Therefore, unless the prescription specifically calls for the recombinant form (HCPCS code J7190 for factors 8), payment is based on the less expensive, non-recombinant forms (HCPCS codes J7191 and J7195).

If carriers or intermediaries determine an unusual billing pattern that demonstrates the provider or supplier is billing much more frequently for the recombinant form than others, they may review the records of the provider/supplier to verify that the records show the blood clotting factors were prescribed by a licensed doctor of medicine, and such physician's written, signed prescription specifies the recombinant form is required.

80.5 - Self-Administered Drugs

(Rev.)

A3-3660.11, A3-3660.12, SNF-536.1, AB-02-72

Fiscal intermediaries and carriers are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

A - Definition of Administered

The term "administered" refers only to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Only injectable (including intravenous) drugs are eligible for inclusion under the "incident to"

benefit. Other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are all considered to be usually self-administered by the patient.

B - Definition of Usually

For the purposes of applying this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and you may not make any Medicare payment for it.

C - Guidelines

1. Absent evidence to the contrary, drugs delivered intravenously should be presumed to be not usually self-administered by the patient.

2. Absent evidence to the contrary, drugs delivered by intramuscular injection should be presumed to be not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:

    - Acute condition - Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition is longer term, it would be more likely that the patient would self-administer the drug.

    - Frequency of administration - How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

3. Absent evidence to the contrary, drugs delivered by subcutaneous injection should be presumed to be self-administered by the patient. However, contractors should examine the use of the particular drug and consider the following factors:

    - Acute condition - Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition is longer term, it would be more likely that the patient would self-administer the drug.

    - Frequency of administration - How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will not pay for such doses. In addition, contractors will not pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

D - Definition of "By the Patient"

The term "by the patient" means Medicare beneficiaries as a collective whole. Contractors must:

- Include only the patients themselves and not other individuals (that is, do not include spouses, friends, or other care-givers).

- Base determination on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications.

- Ignore all instances when the drug is administered on an inpatient basis.

- Make this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.

In evaluating whether beneficiaries as a collective whole self-administer, contractors do not consider individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question. For example, an individual afflicted with dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based.

E - Drugs Subject to Exclusion

Medicare carriers and intermediaries have discretion in applying the criteria in this instruction in determining whether drugs are subject to this exclusion in their local areas. Medicare carriers and intermediaries should post on their Web sites the results of their application of the criteria and notify providers at the earliest opportunity available.

F - Reporting Requirement

Each carrier and intermediary must report to CMS every September 1 and April 1 (i.e., every 6 months) its complete list of injectable drugs that are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered by the patient. Contractors must E-mail this list along with the contractor's name, Medicare identification number and the State(s) affected by the list to: drugdata@cms.hhs.gov.

90 - Claims Processing Rules for Hospital Outpatient Billing and Payment

(Rev.)

90.1 - Blood/Blood Products and Drugs Classified in Separate APCs for Hospital Outpatients

(Rev.)

PM-A-00-42, A-00-61, A-01-50

Proper Billing for Blood Products and Blood Storage and Processing

When a hospital purchases blood or blood products from a community blood bank, or runs its own blood bank and assesses a charge for the blood or blood product, they report blood and blood products in Revenue Code Series 38X "Blood" along with the appropriate blood CMS Healthcare Common Procedure Coding System (HCPCS) code. The amount billed should reflect the hospital's charge. When a hospital does not pay for the blood or blood product, it often incurs an administrative cost from a community blood bank for the bank's processing, storage and related expenses. In this situation, the hospital bills the charge associated with these blood bank storage and processing costs in Revenue Code 390 "Blood Storage/Processing" and reports the HCPCS code assigned to the blood or blood product and the number of units transfused. Payment is based on the Ambulatory Payment Classification (APC) to which the HCPCS code is assigned, times the number of units transfused.

If a hospital purchases blood, or blood products, or runs its own blood bank, it is not appropriate to bill both the blood or blood product in Revenue Code series 38X and an additional blood bank storage and processing charge in Revenue Code 390. A transfusion APC will be paid to the hospital for transfusing blood once per day, regardless of the number of units transfused. Hospitals should bill for transfusion services using Revenue Code 391 "Blood Administration" and HCPCS code 36430 through 36460. The hospital may also bill the laboratory Revenue Codes (30X or 31X) along with the HCPCS codes for blood typing and cross matching and other laboratory services related to the patient who receives the blood.

See Addendum B at http://cms.hhs.gov/regulations/hopps/changecy2003.asp for a list of Blood/blood products and drugs that are classified in separate APCs. Since these are classified in separate APCs, they are not eligible for the transitional pass-through payment system.

90.2 - Changes to Pass-Through Drugs and Biologicals Final Rule

(Rev.)

PM-A-02-026

The CMS updates the payment rates for pass-through drugs and biologicals annually and provides notification of the changes. The all-inclusive list of billable drugs for pass-through payment is included in the current regulation. The most current regulation can be found under the CMS quarterly provider updates on the CMS Web site at: cms.hhs.gov/providerupdate/regsum.asp#1206fc.

90.2.1 - HCPCS Codes Replacements

(Rev.)

PM-A-02-026 §IX.A

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPPS is published quarterly via Program Memorandum. The latest payment rates associated with each APC number may be found in the OPPS PRICER file available on the CMS Web site, as well as in Addendum A and B of OPPS Final Rule. Refer to the current rule found at http://www.cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf.

90.2.2 - Codes Not Recognized for Medicare Under the Hospital OPPS

(Rev.)

PM-A-02-026 §IX.B

Effective April 1, 2002, the following HCPCS codes are no longer recognized under the hospital OPPS. These codes were either assigned to a status indicator of "D" or "E" in the OPPS Final Rule that was published on March 1, 2002. Refer to current rule found at http://www.cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf.

NOTE: These codes, if reported, must be taken in on the claim, along with codes recognized by Medicare, and crossed over to a secondary or supplementary payor.

HCPCS Code	APC	Short Descriptor	Additional Information
C1090	1090	IN 111 chloride, per mCi	Based on consultation with a nuclear pharmaceutical expert, We determined that this radiopharmaceutical agent is never administered in isolation. It is always combined with another agent. Therefore, this code will no longer be reportable under the hospital OPPS.
J1810	7047	Droperidol/fentanyl inj	Review of this specific drug indicates that it is no longer manufactured. Therefore, this code will no longer be reportable under the hospital OPPS.
J9266	843	Pegaspargase/singl dose vial	Review of this specific drug indicates that it is no longer manufactured. Therefore, this code will no longer be reportable under the hospital OPPS.
Q2020	1616	Histrelin acetate	Review of this specific drug indicates that it is no longer manufactured. Therefore, this code will no longer be reportable under the hospital OPPS.

90.2.3 - Additional Drugs Eligible for Pass-Through Payments

(Rev.)

PM-A-02-026 §IX.C

Additional drugs are eligible for pass-through payments. Refer to the most current rule found at: http://www.cms.hhs.gov/providerupdate/regs/cms1206cn2.pdf.

90.2.4 - Changes to Payment Rates and Co-Pay from the March 1, 2002 OPPS Final Rule

(Rev.)

PM-A-02-026 §IX.D

The information below supercedes what was published in the March 1, 2002 Final Rule, and was updated in OPPS PRICER effective April 1, 2002. Only applicable changes are noted below.

HCPCS	APC	Short Descriptor	Old Payment Rate	Old Co-Pay	Corrected Payment Rate	Corrected Co-Pay
C9010	9010	Baclofen refill kit - per 4000 mcg	$ 43.08	$ 6.17	$ 86.17	$ 12.34
J1190	726	Dexrazoxane HCL injection per 250 mg	N/A	24.98	N/A	27.85
J1327	1607	Eptifibatide injection, 5 mg	N/A	1.45	N/A	1.62
J7330	1059	Cultured chondrocytes implnt	14,250.00	2040.00	14,250.00	2,040.00
J7505	7038	Monoclonal antibodies	269.06	38.52	777.31	111.28
Q3007	1624	Sodium phosphate p32	N/A	7.78	N/A	11.61

90.2.5 - Additional Corrections

(Rev.)

PM-A-02-026 §IX.E

The information below identifies additional information or changes to the November 30, 2001 and/or March 1, 2002 Final Rule. These changes are effective April 1, 2002.

HCPCS Code	APC	SI	Short Descriptor	Additional Information
A4642	0704	G	Satumomab pendetide, per dose	Status Indicator changed to "E"
J1561	0905	G	Immune globulin 500 mg	To be used instead of HCPC J1563
Q0081	0120	T	Infusion ther other than che	Still a valid code, not discontinued

90.2.6 - Additional Billing and Reporting Information Related to Pass-Through Drugs Effective April 1, 2002

(Rev.)

PM-A-02-026 §IX.F

Below is additional information for the HCPCS codes listed in the November 30, 2001, and/or March 1, 2002 Final Rule.

HCPCS Code	APC	Short Descriptor	Additional Information
A9504	1602	Technetium tc 99m apcitide [per vial]	Payment rate for this radiopharmaceutical is based on "per vial."
C1064	1064	I-131 **cap**, each add mCi	This code should be reported after the first initial 1-5 mCi. This dosage is to be used for 6 or more capsules and is used in conjunction with C1188. For example, for a patient that received 7 mCi of I-131 capsules, the following codes should be reported: C1188 initial 1-5 mCi Units of service: 1 C1064 each add'l mCi Units of service: 2
C1065	1065	I-131 **sol**, each add mCi	This code should be reported after the first initial 1-6 mCi. For example, for a patient that received 7 mCi of I-131 solution, the following codes should be reported: C1348 initial 1-6 mCi Units of service: 1 C1065 each add'l mCi Units of service: 2

HCPCS Code	APC	Short Descriptor	Additional Information
C1066	1066	In 111 Satumomab pentetide	Under OPPS, A4642 will no longer be reportable effective 04/01/2002. This radiopharmaceutical has been replaced with C1066.
C1188	1188	I-131 **cap**, per 1-5 mCi	This code should be reported for only the initial 1-5 mCi dose of I-131 capsules.
C1305	1305	Apligraf	Only HCPCS code C1305 is reportable under the hospital OPPS. HCPCS J7340 should NOT be reported for Apligraf under the hospital OPPS.
C1348	1348	I-131 **sol**, per 1-6 mCi	This code should be reported for only the initial 1-6 mCi dose of I-131 solution.
C9003	9003	Palivizumab, per 50 mg	The payment rate for this drug was based on a pediatric dose.
C9019	9019	Caspofungin acetate, 5 mg	Dosage Descriptor Alert: The dosage for this code has been changed from 50 mg to 5 mg
C9020	9020	Sirolimus solution, 1 mg	Dosage Descriptor Alert: The descriptor for this code has been changed from Sirolimus tablet, 1 mg to Sirolimus solution 1 mg.
J1565	906	RSV-ivig	The payment rate for this drug was based on a pediatric dose.
Q2008	7027	Fomepizole, 15 mg	Dosage Descriptor Alert: The dosage for this code has been changed from 1.5 mg to 15 mg.

90.2.7 - Typographical Errors from the March 1, 2002 OPPS Final Rule

(Rev.)

PM-A-02-026 §IX.G

The dosage descriptors and short descriptors for the following HCPCS codes were incorrectly listed in Addendum A and B of the March 1, 2002 Final Rule. The information below corrects the information published in the Final Rule.

HCPCS Code	APC	March 1, 2002 Final Rule	Corrected Information
C1079	1079	Addendum A CO 57/58 0.5 mCi	Co 57/58 0.5 uCi
C1094	1094	Addendum A TC 99M Albumin aggr, 1.0 cmCi	TC 99M albumin aggr, 1.0 mCi
C9110	9110	Addendum A Alemtuzumab, per ml	Alemtuzumab, per 10mg/ml
J1626	764	Addendum A Granisetron hcl injection 10 mcg	Granisetron HCL injection 100 mcg
Q0187	1409	Addendum A and B Factor VIII recombinant, per 1.2 mg	Factor viia recombinant
Q3004	1621	Addendum A Xenin xe 133	Xenon xe 133

90.2.8 - Correction to 2002 HCPCS Code Books

(Rev.)

PM-A-02-026 §IX.H

The 2003 Level II HCPCS Code Books contained the following errors in transcription for drugs, biologicals and radiopharmaceuticals. Please ensure that providers are aware of

these errors and that units of service on claims should reflect the **CORRECT** descriptor dosages.

NOTE: mCi or MCI is standard abbreviation for millicurie; uCi is standard abbreviation for microcurie.

For the latest 2003 Level II HCPCS short and long descriptors, refer to the 2003 HCPCS file which can be downloaded from the CMS Web site at: http://cms.hhs.gov/providers/pufdownload/default.asp#alphanu.

Code	Name	Publication Dose	Correct Dose
A9503	Technetium TC 99m medronate	up to 30 microcurie	up to 30 MCI
A9504	Technetium TC 99m apcitide	none noted	per vial
A9505	Thallous chloride TL-201/mci	per microcurie	per MCI
A9508	Iobenguane sulfate I-131 per 0.5 mci	per 0.5 microcurie	per 0.5 MCI
A9511	Technetium Tc 99m depreotide	per microcurie	per MCI
A9600	Strontium-89 chloride per mCi	per microcurie	per MCI
A9605	Samarium sm 153 lexidronanim 50 mCi	per 50 microcurie	per 50 MCI
C1064	I-131 cap, each add mCi	each additional microcurie	each additional MCI (6+ MCI)
C1065	I-131 sol, each add mCi	each additional microcurie	each additional MCI (7+ MCI)
C1188	I-131 cap, per 1-5 mCi	per initial 1-5 microcurie	per initial 1-5 MCI
C1348	I-131 sol, per 1-6 mCi	per initial 1-6 microcurie	per initial 1-6 MCI
C9000	Na chromatecr51, per 0.25mCi	per 0.25 microcurie	per 0.25 MCI
C9013	Co 57 cobaltous chloride	no dose	per 10 uCi
C9100	Iodinated I-131 Albumin	per microcurie	per MCI
C9102	51 Na Chromate, 50mCi	per 50 microcurie	per 50 MCI

Code	Name	Publication Dose	Correct Dose
Q2008	Fomepizole, 15mg	1.5 mg	15 mg
Q3002	Gallium ga 67, per mCi	per microcurie	per MCI
Q3004	Xenon xe 133	per 10 microcuries	per 10 MCI
Q3005	Technetium tc 99m mertiotide	per microcurie	per MCI
Q3006	Technetium tc 99m glucepatate	per 5 microcurie	per 5 MCI
Q3007	Sodium phosphate P32	per microcurie	per MCI
Q3008	Indium 111-in pentetreotide	per 3 microcurie	per 3 MCI
Q3009	Technetium tc99m oxidronate	per microcurie	per MCI
Q3010	Technetium tc99mlabeledrbcs	per microcurie	per MCI
Q3011	Chromic phosphate p32	per microcurie	per MCI
Q3012	Co 57, 0.5 Mci	per 0.5 microcurie	per 0.5 MCI

90.2.9 - Pro-Rata Reduction in Drug and Device Pass-Through Payments

(Rev.)

PM-A-02-026 §X

The final rule published in the "Federal Register" on March 1, 2002, announced a uniform reduction of 63.6 percent to be applied to each of the transitional pass-through payments for drug and devices furnished on or after April 1, 2002. See the "Federal Registers" published on November 1, 2001, November 30, 2001, and March 1, 2002 for a full discussion of these reductions. The reductions were implemented in the OPPS PRICER program for drugs and devices furnished on or after April 1, 2002.

Table 1, as published in the March 1, 2002 "Federal Register," lists the device offset amounts attributable to APCs. These amounts are used in calculating device payments that reflect the pro-rata reduction as illustrated in the example that follows.

Table 1 - Offsets to Be Applied for Each APC That Contains Device Costs

APC	Description	Device Costs (Before Fold-in) Reflected in APC Rate	Additional Device Costs Folded into APC Rate	Total Offset for Device Costs
0032	Insertion of Central Venous/Arterial Catheter	$73.79	$279.97	$353.76
0046	Open/Percutaneous Treatment Fracture or Dislocation	NA	$100.29	$100.29
0048	Arthroplasty with Prosthesis	NA	$514.64	$514.64
0057	Bunion Procedures	NA	$162.89	$162.89
0070	Thoracentesis/Lavage Procedures	NA	$26.47	$26.47
0080	Diagnostic Cardiac Catheterization	$164.27	$134.39	$298.66
0081	Non-Coronary Angioplasty or Atherectomy	$307.06	$362.95	$670.01
0082	Coronary Atherectomy	$242.95	$1,214.06	$1,457.01
0083	Coronary Angioplasty	$528.64	$383.31	$911.95
0085	Level II Electrophysiologic Evaluation	NA	$1,578.03	$1,578.03
0086	Ablate Heart Dysrhythm Focus	NA	$1,320.96	$1,320.96
0087	Cardiac Electrophysiologic Recording/Mapping	NA	$1,980.16	$1,980.16
0088	Thrombectomy	$162.72	$261.14	$423.86
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	$3,175.70	$3,286.36	$6462.06
0090	Insertion/Replacement of Pacemaker Pulse Generator	$2,921.06	$2,123.20	$5,044.26
0094	Resuscitation and Cardioversion	NA	$19.34	$19.34

APC	Description	Device Costs (Before Fold-in) Reflected in APC Rate	Additional Device Costs Folded into APC Rate	Total Offset for Device Costs
0103	Miscellaneous Vascular Procedures	NA	$207.18	$207.18
0104	Transcatheter Placement of Intracoronary Stents	$428.16	$1,256.31	$1,684.47
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	$657.59	$1,049.13	$1,706.72
0107	Insertion of Cardioverter-Defibrillator	$6,803.85	$11,099.62	$17,903.47
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	$6,940.27	$19,607.20	$26,547.47
0111	Blood Product Exchange	NA	$209.72	$209.72
0115	Cannula/Access Device Procedures	NA	$127.26	$127.26
0117	Chemotherapy Administration by Infusion Only	NA	$30.03	$30.03
0118	Chemotherapy Administration by Both Infusion and Other Technique	NA	$28.50	$28.50
0119	Implantation of Devices	NA	$3,348.98	$3,348.98
0120	Infusion Therapy Except Chemotherapy	NA	$35.12	$35.12
0121	Level I Tube Changes and Repositioning	NA	$6.10	$6.10
0122	Level II Tube Changes and Repositioning	$72.55	$214.82	$287.37
0124	Revision of Implanted Infusion Pump	NA	$3,308.76	$3,308.76
0144	Diagnostic Anoscopy	NA	$128.28	$128.28

APC	Description	Device Costs (Before Fold-in) Reflected in APC Rate	Additional Device Costs Folded into APC Rate	Total Offset for Device Costs
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP)	$60.92	$0.00	$60.92
0152	Percutaneous Biliary Endoscopic Procedures	$107.61	$0.00	$107.61
0153	Peritoneal and Abdominal Procedures	NA	$41.23	$41.23
0154	Hernia/Hydrocele Procedures	$108.11	$378.73	$486.84
0161	Level II Cystourethroscopy and other Genitourinary Procedures	NA	$11.20	$11.20
0162	Level III Cystourethroscopy and other Genitourinary Procedures	NA	$319.68	$319.68
0163	Level IV Cystourethroscopy and other Genitourinary Procedures	NA	$901.51	$901.51
0179	Urinary Incontinence Procedures	NA	$3,400.90	$3,400.90
0182	Insertion of Penile Prosthesis	$2,238.90	$569.11	$2,808.14
0202	Level VIII Female Reproductive Proc	$505.32	$1,233.41	$1,738.73
0203	Level V Nerve Injections	NA	$420.98	$420.98
0207	Level IV Nerve Injections	NA	$63.63	$63.63
0222	Implantation of Neurological Device	$4,458.57	$9,599.99	$14,058.56
0223	Implantation of Pain Management Device	$421.33	$3,330.14	$3,751.47
0225	Implantation of Neurostimulator Electrodes	$1,182.00	$11,941.06	$13,123.06

APC	Description	Device Costs (Before Fold-in) Reflected in APC Rate	Additional Device Costs Folded into APC Rate	Total Offset for Device Costs
0226	Implantation of Drug Infusion Reservoir	NA	$3,363.74	$3,363.74
0227	Implantation of Drug Infusion Device	$3,810.46	$2,395.55	$6,206.01
0229	Transcatherter Placement of Intravascular Shunts	$1,074.41	$842.97	$1,917.38
0246	Cataract Procedures with IOL Insert	$146.82	$0.00	$146.82
0259	Level VI ENT Procedures	$12,407.52	$3,836.13	$16,243.65
0264	Level II Miscellaneous Radiology Procedures	NA	$61.59	$61.59
0312	Radioelement Applications	NA	$5,897.22	$5,897.22
0313	Brachytherapy	NA	$998.23	$998.23
0685	Level III Needle Biopsy/Aspiration Except Bone Marrow	NA	$210.75	$210.75
0686	Level V Skin Repair	NA	$465.77	$465.77
0687	Revision/Removal of Neurostimulator Electrodes	NA	$1,444.65	$1,444.65
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver	NA	$6,238.79	$6,238.79
0692	Electronic Analysis of Neurostimulator Pulse Generators	NA	$644.44	$644.44

The following examples illustrate how transitional pass-through payments are calculated for devices and for drugs, taking into account the pro-rata reductions.

A - Example of Transitional Pass-Through Calculation for a Pass-Through Device Furnished On or After April 1, 2002

Device: C1776 Joint device (implantable)

Device cost =	Hospital charge converted to cost = $960
Associated procedure:	CPT 25446 Wrist replacement (APC 48)
Payment rate =	$2211.27
National unadjusted copayment amount =	$725.94
Total offset amount to be applied for each APC that contains device costs =	$514.64

[**Note:** the total offset amount (from Table 1 above) is wage and discount factor adjusted before it is subtracted from the device cost.]

Device cost adjusted by total offset amount:	$960-$514.64 = $445.36
Device cost after adjustment for pro rata reduction:	$445.36 x .364 = $162.11
Medicare program payment (before wage index adjustment) for APC 48:	$2211.27 - 725.94 = $1485.33
Medicare program payment for pass-through device C1776 =	$162.11
Beneficiary copayment liability:	$725.94

Total amount received by provider for APC 48 and pass-through device C1776

$1485.33	(Medicare program payment for CPT code 25446)
725.94	(Beneficiary unadjusted copayment amount for CPT code 25446)
162.11	(Transitional pass-through payment for device)
$2373.38	

B - Example of Transitional Pass-Through Calculation for a Pass-Through Drug Furnished On or After April 1, 2002

APC 1613 Trastuzumab, 10 mg

Unadjusted Copayment Amount =	$7.56
Payment rate =	$52.83
Non-pass-through portion = (5 x copay) =	5 x 7.56 = $37.80
Pass-through portion =	$52.83 - $37.80 = $15.03

Pass-through portion after adjustment for 63.6 percent pro rata reduction

$15.03 x .364 =	$5.47

Total payment to provider for APC 1613 after pro rata reduction:

$5.47	(pass-through portion adjusted for pro rata reduction)
37.80	(non-pass-through portion)
$43.27	(total payment to provider)
- 7.56	(beneficiary copayment)
$35.71	(total Medicare program payment)