CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 248 **Date: JULY 23, 2004**

CHANGE REQUEST 3232

I. SUMMARY OF CHANGES: Carriers and DMERCs/SADMERC – Beginning January 1, 2005, MMA mandates that drugs and biologicals not paid on cost or prospective payment basis shall be paid based on Average Sales Price (ASP).

NEW/REVISED MATERIAL - EFFECTIVE DATE: August 23, 2004
IMPLEMENTATION DATE: January 1, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	17/Table of Contents
R	17/10/Payment Rules for Drugs and Biologicals
N	17/20.1/MMA Drug Pricing-Average Sales Price
R	17/20.2/Single Drug Pricer (SDP)
R	17/20.3/Calculation of the Payment Allowance Limit for DMERC Drugs
R	17/20.4/Calculation of the AWP
R	17/20.5/Detailed Procedures for Determining AWPs and the Drug Payment Allowance Limits
R	17/20.5.1/Background
R	17/20.5.2/Review of Sources for Medicare Covered Drugs and Biologicals
R	17/20.5.3/Use of Generics
R	17/20.5.4/Find the Strength and Dosage
R	17/20.5.5/Restrictions
R	17/20.5.6/Inherent Reasonableness for Drugs and Biologicals
R	17/20.5.7/Injection Services
R	17/20.5.8/Injections Furnished to ESRD Beneficiaries

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

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

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-04	Transmittal: 248	Date: July 23, 2004	Change Request 3232

SUBJECT: DMERC/Local Carriers/SADMERC – Drug Pricing Limits as of January 1, 2005

I. GENERAL INFORMATION

A. Background: Per Section 303 of MMA of 2003, beginning 1/1/04 through 12/31/04, drugs and biologicals not paid on a cost or prospective payment basis are paid based on various standards specified in the statute, although the default payment allowance limit standard is 85 percent of AWP.

B. Policy: Per MMA of 2003, beginning 1/1/05, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on the Average Sales Price (ASP) plus 6%. CMS will supply contractors with an ASP drug pricing file for paying drugs beginning 1/1/05. Payment shall be based on the lower of the submitted charge or the ASP price. Payment will continue to be based on date of service. The ASP payment allowance limits drug file shall be provided to the contractors by CMS quarterly**.** Contractors will continue to price drugs not on the ASP pricing file, including compounded drugs. Instructions for the methodology to be used by contractors will be issued shortly. Contractors shall continue to take issues and problems to their Regional Office Contacts. The Regional Office will contact CMS if necessary.

C. Provider Education: A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their website and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Further, CMS shall waive the 30 day requirement for provider notification of payment allowance limits. However, contractors shall post the drug payment allowance limits as soon as possible.

II. BUSINESS REQUIREMENTS

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

Requirement #	Requirements	Responsibility
3232.1	Contractors shall not price drugs except for drugs not priced in the ASP Drug Pricing File (new drugs not on the file, other drugs not on	Carriers, DMERCs, SADMERC

	the file, and compound drugs. Methodology for pricing these drugs will follow in another CR.)	
3232.2	Contractors shall adjudicate claims based on the ASP Drug Pricing File beginning January 1, 2005. The drug pricing payment allowance limit file shall be provided to contractors by CMS.	Carriers, DMERCs
3232.3	Contractors shall post the payment allowance limits as soon as possible. However, the 30 day requirement is waived.	Carriers, DMERCs
3232.4	Contractors shall receive, load, and utilize the ASP drug pricing files quarterly. The file will be sent to contractors in excel format 30 days prior to the appropriate quarter. This file shall have no regional payment adjustments.	Carriers, DMERCs
3232.5	Contractors shall continue to contact their Regional Offices with problems and issues.	Carriers, DMERCs
3232.6	For any drug for which a contractor calculates a payment allowance limit the contractor shall forward the new drug name and payment allowance limit to CMS for inclusion in the next quarterly update. Forward this information to MBaldo@cms.hhs.gov.	Carriers, DMERCs

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

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

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: August 23, 2004. **Implementation Date:** January 1, 2005. **Pre-Implementation Contact(s):** Joanne Spalding and Marjorie Baldo **Post-Implementation Contact(s):** Appropriate RO contact.	**These instructions shall be implemented within your current operating budget**

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

Table of Contents
(Rev.248, 07-23-04)

10 - Payment Rules for Drugs and Biologicals

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (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 Centers for Medicare & Medicaid Services (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 national drug codes (NDC) are required by the Health Insurance Portability and Accountability Act (HIPAA). A separate payment may be made for hospital inpatients, who receive hemophilia clotting factors (but not SNF). See Chapter 3 for instructions on billing inpatient hospital hemophilia clotting factors.

All hospital outpatient drugs are excluded from SDP because the payment allowance for such drugs is determined by a different procedure. Most drugs furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (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 the Balanced Budget Refinement Act of 1999 (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. The 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 Health Insurance Common Procedure Coding System (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. OPPS PRICER includes a table of drugs and prices and provides the intermediary (FI) 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 and biologicals not paid on cost or prospective payment basis have been paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that have been paid on this basis include but are not limited to drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors. The Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) of 2003 changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. Beginning January 1, 2004, through December 31, 2004, such drugs or biologicals are paid based on various standards specified in the statute, although the default standard is 85 percent of AWP. See §20, below for a full discussion of the basis for drugs in this category during 2004.

For services furnished on or after January 1, 2005, the payment allowance limit for drugs and biologicals is based on the Average Sales Price (ASP). This pricing file will be provided to contractors by CMS

20.1 – MMA Drug Pricing – Average Sales Price

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

In general, CMS establishes a single, national payment limit for FI and carrier payment for each Medicare-covered drug whose payment is determined based on the methodology described above.

*The CMS provides **an ASP** file to each carrier and FI for pricing drugs. For services furnished during 2004, the carrier shall develop payment limits using the above methodology only when CMS does not supply a payment limit for the drug. Each FI and carrier must accept the **ASP** files made available by CMS for pricing bills/claims for any drug identified on the process files.*

Beginning January 1, 2005, the payment limit for Part B drugs and biologicals will be based on the Average Sales Price (ASP). Drugs will be paid based on the lower of the submitted charge or the ASP.

These drugs continue to be priced based on date of service. These drug payment limits will be distributed to contractors by CMS. CMS will update and provide this file quarterly. Carriers/DMERCs/SADMERC shall develop payment limits when CMS does not supply a payment limit for the drug on the file.

20.*2* - Single Drug Pricer (SDP)

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

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 (RHHIs) and durable medical equipment regional carriers (DMERCs), as follows:

1. "HCPCS" Drug Pricing File
   a. 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 30 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

2. "Not otherwise classified" (NOC) Drug Pricing File
   a. CMS furnishes a NOC SDP file for drugs "not otherwise classified." 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., the initial NOC file's filename was "ndpf0301.xls").

c. The CMS makes a revised NDPF available approximately 30 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

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

3. The CMS furnishes a pricing documentation file (PDF) that contains only new drugs and biologicals for which a Medicare price has been established since the previous quarter:

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.

Except as specifically noted, each FI and carrier will:

- Upon receiving the quarterly update files, execute its normal update process using the SDP files. If necessary, the contractor shall process manually to implement SDP file prices effective with the beginning of the following quarter.
- Compare the prices it paid previously with the prices shown on the prior SDP file; taking note of the unit pricing quantity shown on the applicable SDP file and comparing it to the unit pricing quantity to ensure that any apparent price changes are real.
    - Carriers must notify physicians of price changes.
    - FIs 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.
- Advise the RO of any price on a SDP file it believes is not correct.
- Not substitute its 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, 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 NDC.
    - Report to the RO, on or before March 1 of each year, 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.
- Carriers and FIs: Publish current SDP prices on their Web site immediately upon receipt of the file from CMS.
- FIs: As needed on a quarterly basis and within seven days of receipt of the SDP files, request, from carriers, prices of drugs that carriers may price separately.
    - Carriers: Upon request, on a quarterly basis and within seven days of any such request, furnish to FIs within jurisdiction, free of charge, the subset of files, which includes drugs that are priced separately.
- FIs and Carriers: 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.
- The MCS Carrier shared systems shall maintain eight fee screens/pricing files (a current period and seven prior periods) for Part B "incident to" drugs billed to carriers for payment on a fee-for-service basis. (NOTE: VIPS is waived and will continue to carry 5 pricing periods)
- Since they post the updated SDP file to their Web site upon receipt from CMS, carriers are waived from the requirement to give 30 days advance notice for fee schedule changes with respect to drugs.
- SDP does not preclude the use of inherent reasonableness or the establishment of local medical review policies, including the use of a least costly alternative.
    - If a least costly alternative is determined and a process for the least costly alternative exists on the SDP, the SDP price for the least costly alternative must be used.
- Medicare coverage determinations are independent of the SDP. The presence or absence of a price for a particular drug in the SDP is irrelevant to Medicare coverage determinations.
- EPO=Q codes are included in the SDP, applicable to physician claims. The statutory limit for EPO applies to nonphysician claims.
- "Unit Measurement" means the amount of whatever measurement is used in the code description (e.g., milligrams (mg)).

ROs:

1. Advise carriers concerning the implementation of the SDP.
2. Respond to questions about drug price changes.
3. Respond to questions about the implementation of the AWP pricing methodology.

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.*3* – Calculation of the Payment Allowance Limit for DMERC Drugs

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

Payments for drugs billed to the DMERCs will be based on the implementation of the MPDIMA, beginning January 1, 2004, and will be paid at 85 percent of the AWP for HCPCS payment amounts based on the April 1, 2003 fee schedule. Exceptions to this calculation are as follows:

The payment limits for infusion drugs furnished through an item of durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.

- The payment limits for new drugs or biologicals will be 95 percent of the AWP. A new drug is defined as an unlisted drug (not currently covered by a HCPCS code) that was FDA approved subsequent to April 1,2003. A drug would not be considered new if: The brand or manufacturer of the drug changed; a new formulation of the vial size is developed ; or the drug received a new indication.

The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWPs specified on Table 1 in §20 .

Payment limits determined under this instruction shall not be updated during 2004.

20.*4* - Calculation of the AWP

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

See Business Requirements and Excel Spreadsheets at
http://www.medicaid.com/manuals/pm_trans/R54CP.pdf
http://www.medicaid.com/manuals/pm_trans/R55CP.pdf

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, or there may be no source.

- 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 AWP, carriers multiply it by 0.85 or 0.95, or other percentage, as applicable, and round to the nearest penny. This is the drug payment allowance limit. Carriers round it in accordance with standard rounding procedure. Part B coinsurance and deductible requirements apply.
In applying this procedure, carriers use the package sizes that are most commonly used for the most frequently administered dosage of the drug.
Intermediaries get drug prices from the carrier for drugs not listed on the Single Drug Pricer.

20.*5* - Detailed Procedures for Determining AWPs and the Drug Payment Allowance Limits

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

20.*5*.1 - Background

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

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 and MPDIMA, Section 303(b))
The earliest drug payment allowance limit effective in 2004 will not be subsequently updated during 2004. When limits are initially established, carriers inform FIs and the provider community as described in paragraph §30 below.

20.*5*.2 - Review of Sources for Medicare Covered Drugs and Biologicals

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

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 of the Medicare Benefit 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.*5* 3 - Use of Generics

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

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.*5*. 4 - Find the Strength and Dosage

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

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.

20.5.5 - Restrictions

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

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 is 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 March 1994).

20.5.6 - Inherent Reasonableness for Drugs and Biologicals

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

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 Chapter 23 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 FIs 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. The 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

20.5.7 – *Injection Services*

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

Where the sole purpose of an office visit was for the patient to receive an injection, payment may be made only for the injection service (if it is covered). Conversely, injection services (codes 90782, 90783, 90784, 90788, and 90799) included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time. Pay separately for those injection services only if no other physician fee schedule service is being paid. However, pay separately for cancer chemotherapy injections (CPT codes 96400-96549) in addition to the visit furnished on the same day. In either case, the drug is separately payable. All injection claims must include the specific name of the drug and dosage. Identification of the drug enables you to pay for the services.

20.5.8 – Injections Furnished to ESRD Beneficiaries

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

When an ESRD beneficiary is given a renal related injection outside the ESRD facility or provider-setting, it should be administered by the beneficiary's monthly capitation payment (MCP) physician or his/her staff as "incident to" such physician's services. There is no additional allowance for the physician or his staff, e.g., an office nurse. This is because payment for the administration of a renal-related injection to a dialysis patient is included in the physicians' monthly capitation payment (MCP).
The regulations governing Medicare payment for physicians' ESRD services (42 CFR 405.542) require that all physicians' outpatient ESRD-related services except declotting shunts be paid under the MCP. If a physician, other than the patient's MCP physician, administers a renal-related injection, the other physician must look to the MCP physician for compensation for the services.
Although an additional allowance for the administration of a renal-related injection to a dialysis patient may not be made, the patient's MCP physician or a physician other than

the MCP physician may submit claims and be paid for the drug itself as well as supplies, e.g., needles and syringes, used to administer the drug.

EXAMPLE

Dr. Jones is Mr. White's MCP physician. Dr. Jones is unable to furnish the regular EPO injections his patient needs three times a week. It is Dr. Jones' responsibility to compensate the physician who administers the injections. The administering physician submits claims for the injectable and necessary supplies. In this case, the carrier makes a reasonable monthly allowance, e.g., $3 for the cost of supplies (i.e., syringes and needles).