

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1650	Date: DECEMBER 19, 2008
	Change Request 6288

SUBJECT: January 2009 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

I. SUMMARY OF CHANGES: Section 303(c) of the Medicare Modernization Act of 2003 revised the payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis. The vast majority of drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor. The initial release of this RUN can be found in Chapter 17, Section 20.1 of the IOM.

New / Revised Material

Effective Date: January 1, 2009

Implementation Date: January 5, 2009

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	Chapter / Section / Subsection / Title
N/A	

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

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

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

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

Attachment – Recurring Update Notification

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SUBJECT: January 2009 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

Effective Date: January 1, 2009

Implementation Date: January 5, 2009

I. GENERAL INFORMATION

A. Background: Section 303(c) of the Medicare Modernization Act of 2003 revised the payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis. The vast majority of drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor.

The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the OPPTS are incorporated into the Outpatient Code Editor (OCE) through separate instructions.

As announced in late 2006, the CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of this effort, we have also reviewed how we have operationalized the terms “single source drug,” “multiple source drug,” and “biological product” in the context of payment under section 1847A. For the purposes of identifying “single source drugs” and “biological products” subject to payment under section 1847A, generally CMS (and its contractors) will utilize a multi-step process. We will consider:

- The FDA approval,
- Therapeutic equivalents as determined by the FDA, and
- The date of first sale in the United States.

For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of “not otherwise classified” HCPCS codes.

B. Policy: In general, beginning January 1, 2005, the payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106% of the ASP. Further, beginning January 1, 2006, payment allowance limits are paid based on 106% of the ASP for the following:

- ESRD drugs (when separately billed by freestanding and hospital-based ESRD facilities), and
- Specified covered outpatient drugs and drugs and biologicals with pass-through status under the OPSS.

Beginning January 1, 2008, under the OPSS, payment allowance limits for specified covered outpatient drugs are paid at ASP+5%. Beginning January 1, 2009, under the OPSS, payment allowance limits for specified covered outpatient drugs are paid at ASP+4%. Drugs and biologicals with pass-through status under the OPSS continue to have a payment allowance limit of 106% of the ASP. CMS will update the payment allowance limits quarterly. There are exceptions to this general rule as summarized below.

(1) The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a prospective payment basis, are determined in the same manner the payment allowance limits were determined on October 1, 2003. Specifically, the payment allowance limits for blood and blood products are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment allowance limits will be updated on a quarterly basis. Blood and blood products furnished in the hospital outpatient department are paid under OPSS at the amount specified for the APC to which the product is assigned.

(2) The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment on or after January 1, 2005, will continue to be 95 percent of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. The payment allowance limits will not be updated in 2008. The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service.

(3) The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost.

(4) The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs and biologicals that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published wholesale acquisition cost (WAC) or invoice pricing, except under OPSS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in Pub. 100-04, Chapter 17, Drugs and Biologicals, for calculating the AWP but substitute WAC for AWP. The payment limit is 100 percent of the lesser of the lowest-priced brand or median generic WAC. For 2006, the blood clotting furnishing factor of \$0.146 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file. For 2007, the blood clotting furnishing factor of \$0.152 per I.U. is added to the payment amount for the blood clotting factor when the

blood clotting factor is not included on the ASP file. For 2008, the blood clotting furnishing factor of \$0.158 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file. For 2009, the blood clotting furnishing factor of \$0.164 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file.

At the contractors' discretion, contractors may contact CMS to obtain payment limits for drugs and biologicals not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site.

(5) The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs and biologicals that were first sold on or after January 1, 2005. At the contractors' discretion, contractors may contact CMS to obtain payment limits for new drugs and biologicals not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site. For 2006, the blood clotting furnishing factor of \$0.146 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file. For 2007, the blood clotting furnishing factor of \$0.152 per I.U. is added to the payment amount for a new blood clotting factor when a new blood clotting factor is not included on the ASP file. For 2008, the blood clotting furnishing factor of \$0.158 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file.

(6) The payment allowance limits for radiopharmaceuticals are not subject to the ASP payment methodology. Contractors should determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Radiopharmaceuticals furnished in the hospital outpatient department are paid charges reduced to cost by the hospital's overall cost to charge ratio.

Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir

Physicians (or a practitioner described in Section 1842(b) (18) (C)) may be paid for filling or refilling an implantable pump or reservoir when it is medically necessary for the physician (or other practitioner) to perform the service. Contractors must find the use of the implantable pump or reservoir medically reasonable and necessary in order to allow payment for the professional service to fill or refill the implantable pump or reservoir and to allow payment for drugs furnished incident to the professional service. If a physician (or other practitioner) is prescribing medication for a patient with an implantable pump, a nurse may refill the pump if the medication administered is accepted as a safe and effective treatment of the patient's illness or injury; there is a medical reason that the medication cannot be taken orally; and the skills of the nurse are needed to infuse the medication safely and effectively.

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	in accordance with the policy described in this CR and JSM-06391.										
6288.6.1	FIs should seek payment allowances not on the ASP file from their local carrier for drugs and biologicals.	X		X		X	X				
6288.7	At the contractor's discretion, contractors should contact CMS to obtain payment limits for drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site.	X	X	X	X	X					
6288.7.1	If the payment limit is available from CMS, contractors shall substitute CMS-provided payment limits for pricing, based on WAC or invoice pricing.	X	X	X	X	X	X	X			
6288.7.1.1	Contractors shall contact CMS via e-mail at sec303aspdata@cms.hhs.gov .	X	X	X	X	X					
6288.7.1.2	Contractors shall include "Pricing Request" in the subject line.	X	X	X	X	X					
6288.7.2	At the contractor's discretion, contractors should contact CMS to request additions or deletions of billing codes, drugs and/or payment limits to the ASP and/or ASP NOC files, including payment limits for DME infused drugs.	X	X	X	X	X					
6288.7.2.1	Contractors shall contact CMS via e-mail at sec303aspdata@cms.hhs.gov .	X	X	X	X	X					
6288.7.2.2	Contractors shall include "Pricing Request" in the subject line.	X	X	X	X	X					
6288.8	Contractors shall make separate payment for the blood clotting factor furnishing fee when separate payment for the blood clotting factor is allowed and the payment limit for the blood clotting factor is not included on the ASP or NOC file.	X		X	X	X					
6288.8.1	For dates of service January 1, 2006, through December 31, 2006, the blood clotting factor furnishing fee of \$0.146 per I.U. is added to the payment limit for the blood clotting factor.	X		X	X	X					
6288.8.2	For dates of service January 1, 2007, through	X		X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	December 31, 2007, the blood clotting factor furnishing fee of \$0.152 per I.U. is added to the payment limit for the blood clotting factor.										
6288.8.3	For dates of service January 1, 2008, through December 31, 2008, the blood clotting factor furnishing fee of \$0.158 per I.U. is added to the payment limit for the blood clotting factor.	X		X	X	X					
6288.8.4	For dates of service January 1, 2009, through December 31, 2009, the blood clotting factor furnishing fee of \$0.164 per I.U. is added to the payment limit for the blood clotting factor.	X		X	X	X					
6288.9	Contractors shall use the most current version available of the Medicare Contractor Reporting Template for Part B drugs to report information on Medicare Part B drugs not paid on a cost or prospective payment basis when payment limits are not listed in the quarterly drug pricing ASP and NOC files, or in the OPPS Pricer.	X	X	X	X	X					
6288.9.1	Contractors shall use the template to report pricing information for the NOC drugs not included on the Medicare Part B NOC pricing file, any HCPCS drug codes not on the ASP file, and OPPS drugs not in the OPPS Pricer.	X	X	X	X	X					
6288.9.2	Contractors shall list all drugs that were priced since the last submitted report.	X	X	X	X	X					
6288.9.3	Contractors shall list each drug priced on the report only once.	X	X	X	X	X					
6288.9.4	For compounded drugs, contractors shall report the name of each drug in the compounded product.	X	X	X	X	X					
6288.9.5	Contractors shall prepare and submit the reports so that each report covers approximately 30 days of pricing activity.	X	X	X	X	X					
6288.9.6	Contractors shall report drugs omitted from previous reports in the next report.	X	X	X	X	X					
6288.9.7	Contractors shall complete the report in its	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	entirety.										
6288.9.8	Contractors do not need to report radiopharmaceuticals.	X			X						
6288.9.9	FIs shall report pricing information for drugs, biologicals, and radiopharmaceuticals that are billed using C9399.	X		X		X					
6288.10	Contractors shall download the most current version available of the template from the CMS Web site at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01_overview.asp#TopOfPage .	X	X	X	X	X					
6288.11	Contractors shall complete the template on a monthly basis.	X	X	X	X	X					
6288.11.1	The template shall be in MS Excel format.	X	X	X	X	X					
6288.11.2	Contractors shall send the completed template to sec303aspdata@cms.hhs.gov on the first business day of the month.	X	X	X	X	X					
6288.11.3	If the contractor has not priced any drugs since the last submitted report, in lieu of using the template, the contractor shall send an email to Sec303aspdata@cms.hhs.gov stating that the contractor has no drug pricing to report.	X	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6288.12	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, Glenn.McGuirk@cms.hhs.gov

Post-Implementation Contact(s): Glenn McGuirk, Glenn.McGuirk@cms.hhs.gov

VI. FUNDING

A. For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC):

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

B. *For Medicare Administrative Contractors (MAC):*

The Medicare Administrative Contractor (MAC) is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as changes to the MAC Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by E-mail, and request formal directions regarding continued performance requirements.