CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 974

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: JUNE 9, 2006

Change Request 5110

SUBJECT: July 2006 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File, Effective July 1, 2006, and Revisions to January 2006 and April 2006 Quarterly ASP Medicare Part B Drug Pricing Files

I. SUMMARY OF CHANGES: This instruction informs Medicare contractors to download the July 2006 ASP drug pricing file as well as the revised January 2006 and April 2006 ASP drug pricing file for Medicare Part B drugs.

NEW/REVISED MATERIAL

EFFECTIVE DATE: July 1, 2006

IMPLEMENTATION DATE: July 3, 2006

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

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 974	Date: June 9, 2006	Change Request 5110

SUBJECT: July 2006 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File, Effective July 1, 2006, and Revisions to January 2006 and April 2006 Quarterly ASP Medicare Part B Drug Pricing Files

I. GENERAL INFORMATION

A. Background: Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revises the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. Per the MMA, beginning January 1, 2005, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor. Additionally, in 2006, all ESRD drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on the ASP methodology. 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.

B. Policy:

ASP Methodology

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 percent of the ASP. Beginning January 1, 2006, the payment allowance limits for all ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent 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 OPPS 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. The payment allowance limits will not be updated in 2006. 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.

(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 that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application approved by the Food and Drug Administration, are based on the published wholesale acquisition cost (WAC) or invoice pricing. In determining the payment limit based on WAC, the contractors follow the methodology specified in Chapter 17, Drugs and Biologicals, of the Medicare Claims Processing Internet Only Manual for calculating the Average Wholesale Price (AWP) but substitute WAC for AWP. The payment limit is 100 percent of the lesser of the lowest brand or median generic WAC. At the contractors' discretion, contractors may 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. 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 that are produced or distributed under a new drug 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. This policy applies only to new drugs that were first sold on or after January 1, 2005.

(6) The payment allowance limits for radiopharmaceuticals are not subject to ASP. 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.

On or after June 20, 2006, revised January 2006 and April 2006 ASP and NOC payment files and the July 2006 ASP and NOC files will be available for download. The revised January 2006 payment allowance limits apply to dates of service January 1, 2006 through March 31, 2006. The revised April 2006 payment allowance limits apply to dates of service April 1, 2006 through June 30, 2006. The July 2006 payment allowance limits apply to dates of service July 1, 2006 through September 30, 2006.

The payment limits included in the revised ASP and NOC payment files supersede the payment limits for these codes in any publication published prior to this document.

NOTE: The absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. The local Medicare contractor processing the claim shall make these determinations.

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.

This instruction clarifies that payment for drugs furnished incident to the filling or refilling of an implantable pump or reservoir is determined under the ASP methodology, as described above. Pricing for compounded drugs is performed by the local contractor.

II. BUSINESS REQUIREMENTS

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

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5110.1	The July 2006 and revised January 2006 and April 2006 ASP drug pricing files for Medicare Part B drugs will be available via the CMS Data Center (CDC). Contractors shall download the revised January 2006 ASP drug pricing file through the CDC on or after June 20, 2006. Final File: MU00.@BF12390.ASP.CY06.JAN.V0620	X	X	X	X	X	X	X		
5110.1.1	Contractors shall overlay the previous January 2006 file with the new January 2006 ASP drug pricing file.	X	X	X	X	X	X	X		
5110.1.2	Contractors shall use the revised January 2006 ASP and NOC drug pricing files to pay for Medicare Part B drugs effective January 1, 2006 through March 31, 2006.	X	X	X	X	X	X	X		
5110.1.3	Contractors shall download the revised April 2006 ASP drug pricing file through the CDC on or after June 20, 2006. Final File:	X	X	X	X	X	X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	MU00.@BF12390.ASP.CY06.APR.V0620									
5110.1.4	Contractors shall overlay the previous April 2006 file with the new April 2006 ASP drug pricing file.	X	X	X	X	X	X	X		
5110.1.5	Contractors shall use the revised April 2006 ASP and NOC drug pricing files to pay for Medicare Part B drugs effective April 1, 2006 through June 30, 2006.	X	X	X	X	X	X	X		
5110.1.6	Contractors shall download the new July 2006 ASP drug pricing file through the CDC on or after June 20, 2006. Final File: MU00.@BF12390.ASP.CY06.JUL.V0620	X	X	X	X	X	X	X		
5110.2	Contractors shall not search and adjust claims that have already been processed unless brought to their attention.	X	X	X	X	X	X	X		
5110.3	Notification of successful receipt shall be sent via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., carrier/DMERC/fiscal intermediary name and number).	X	X	X	X	X	X	X		
5110.4	The ASP and NOC drug pricing files will contain the applicable payment allowance limits (i.e., 106% ASP, 106% WAC, or 95% AWP); therefore, Medicare contractors shall not make any additional payment calculations.	X	X	X	X	X	X	X		
5110.5	For any drug or biological not listed in the ASP or NOC drug pricing files, contractors shall determine the payment allowance limits in accordance with the policy described in this CR and JSM-06391.	X	X	X	X	X	X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5110.5.1	FIs should seek payment allowances from their local carrier.	X	X		X	X	X	X		
5110.6	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	X	X		
5110.6.1	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		
5110.6.1.1	Contractors shall contact CMS via e-mail at sec303aspdata@cms.hhs.gov.	X	X	X	X	X	X	X		
5110.6.1.2	Contractors shall include "Pricing Request" in the subject line.	X	X	X	X	X	X	X		
5110.7	Contractors shall use 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	X	X		
5110.7.1	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	X	X		
5110.7.2	Contractors shall list all drugs that were priced since the last submitted report.	X	X	X	X	X	X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5110.7.3	Contractors shall list each drug priced on the report only once, unless the drug was priced via invoice and the price is not the same.	X	X	X	X	X	X	X		
5110.7.4	For compounded drugs, contractors shall report the name of each drug in the compounded product that required manual pricing, each time the drug price changed.	X	X	X	X	X	X	X		
5110.7.5	Contractors shall prepare and submit the reports so that each report covers approximately 30 days of pricing activity.	X	X	X	X	X	X	X		
5110.7.6	Contractors shall report drugs omitted from previous reports in the next report.	X	X	X	X	X	X	X		
5110.7.7	Contractors shall complete the report in its entirety.	X	X	X	X	X	X	X		
5110.7.8	Carriers do not need to report radiopharmaceuticals.			X						
5110.7.9	FIs shall report drugs, biologicals, and radiopharmaceuticals that are billed using C9399.	X								
5110.8	Contractors shall download the template from the CMS Web site at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp.	X	X	X	X	X	X	X		
5110.9	Contractors shall complete the template on a monthly basis.	X	X	X	X	X	X	X		
5110.9.1	The template shall be in MS Excel format.	X	X	X	X	X	X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5110.9.2	Contractors shall send it to sec303aspdata@cms.hhs.gov on the first business day of the month.	X	X	X	X	X	X	X		

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5110.10	A provider education article related to this instruction will be available at www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X					

IV. 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

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: July 1, 2006 **Implementation Date:** July 3, 2006 **Pre-Implementation Contact(s):** Angela Mason, angela.mason@cms.hhs.gov or Catherine Jansto, Catherine.jansto@cms.hhs.gov **Post-Implementation Contact(s):** Appropriate Regional Office	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

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