



**News Flash** – A Special Edition MLN Matters provider education article is now available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0904.pdf> on the CMS website. This Special Edition article alerts providers regarding the implementation of HIPAA 5010 which presents substantial changes in the content of the data that providers submit with their claims as well as the data available to them in response to their electronic inquiries and outlines how providers need to plan for implementation of these changes.

MLN Matters® Number: MM6471

Related Change Request (CR) #: 6471

Related CR Release Date: May 15, 2009

Effective Date: July 1, 2009

Related CR Transmittal #: R1737

Implementation Date: July 6, 2009

## July 2009 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

### Provider Types Affected

All physicians, providers and suppliers who submit claims to Medicare contractors (Medicare Administrative Contractors (MACs), Fiscal Intermediaries (FIs), carriers, Durable Medical Equipment Medicare Administrative Contractors (DME MACs) or Regional Home Health Intermediaries (RHHIs)) for services provided to Medicare beneficiaries.

### What You Need to Know

This article is based on Change Request (CR) 6471 and instructs Medicare contractors to download and implement the July 2009 ASP drug pricing file for Medicare Part B drugs; and if released by the Centers for Medicare & Medicaid Services (CMS), also the revised April 2009, January 2009, October 2008 and July 2008, files. They will use the July 2009 ASP and not otherwise classified (NOC) drug pricing files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 6, 2009 with dates of service July 1, 2009, through September 30, 2009.

### Background

#### Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

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. Beginning January 1, 2005, the vast majority of drugs and biologicals not paid on a cost or prospective payment basis are paid based on the ASP methodology, and pricing for compounded drugs has been performed by the local contractor.

For the purpose of identifying “single source drugs” and “biological products” subject to payment under section 1847A, CMS (and its contractors) will generally utilize a multi-step process that will consider:

- The Food and Drug Administration (FDA) approval;
- Therapeutic equivalents as determined by the FDA; and
- The date of first sale in the United States.

The payment limit for the following will be based on the pricing information for products marketed or sold under the applicable FDA approval:

- A biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval), or
- A single source drug (a drug for which there are not 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.

As appropriate, a unique Healthcare Common Procedure Coding System (HCPCS) code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of NOC HCPCS codes.

### **ASP Methodology**

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 percent of the ASP. Further, beginning January 1, 2006, payment allowance limits are paid based on 106 percent of the ASP for:

- End Stage Renal Disease (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 OPPS.

Beginning January 1, 2008, under the OPPS, payment allowance limits for specified covered outpatient drugs are paid at ASP+5%. Beginning January 1, 2009, under the OPPS, payment allowance limits for specified covered outpatient drugs are paid at ASP+4%. Drugs and biologicals with pass-through status under the OPPS continue to have a payment allowance limit of 106% of the ASP. CMS

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will update the payment allowance limits quarterly. There are exceptions to this general rule and they are stated in the Medicare Claims Processing Manual, Chapter 17, Section 20.1.3 and may be reviewed at <http://www.cms.hhs.gov/manuals/downloads/clm104c17.pdf> on the CMS website.

### Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir

Physicians (or a practitioner described in Section 1842(b) (18) (C) of the Social Security Act) 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. Medicare 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. 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, except that pricing for compounded drugs is done by your local Medicare contractor.

### Use of Quarterly Payment Files

The following table shows how the quarterly payment files will be applied:

Payment Allowance Limit Revision Date	Applicable Dates of Service
July 2009 ASP and ASP NOC files	July 1, 2009, through September 30, 2009
April 2009 ASP and ASP NOC files	April 1, 2009, through June 30, 2009
January 2009 ASP and NOC Files	January 1, 2009, through March 31, 2009
October 2008 ASP and NOC Files	October 1, 2008, through December 31, 2008
July 2008 ASP and NOC files	July 1, 2008, through September 30, 2008

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**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 makes these determinations

## Additional Information

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If you have questions, please contact your Medicare contractor at their toll-free number which may be found at

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

The official instruction (CR6471) issued to your Medicare carrier, FI, RHHI, MAC, or DME MAC is available at

<http://www.cms.hhs.gov/Transmittals/downloads/R1737CP.pdf> on the CMS website.

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