



**News Flash – It’s Not Too Late to Give and Get the Flu Shot!** In the United States, the peak of flu season typically occurs anywhere from late December through March; however, flu season can last as late as May. Each office visit presents an opportunity for you to talk with your patients about the importance of getting an annual flu shot and a one time pneumococcal vaccination. Protect yourself, your patients, and your family and friends by getting and giving the flu shot. **Don’t Get the Flu. Don’t Give the Flu.** Remember - Influenza and pneumococcal vaccinations plus their administration are covered Part B benefits. Note that influenza and pneumococcal vaccines are NOT Part D covered drugs. Health care professionals and their staff can learn more about Medicare’s Part B coverage of adult immunizations and related provider education resources, by reviewing Special Edition *MLN Matters* article SE0838 <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0838.pdf> on the CMS website.

MLN Matters Number: MM6380

Related Change Request (CR) #: 6380

Related CR Release Date: February 20, 2009

Effective Date: April 1, 2009

Related CR Transmittal #: R1685CP

Implementation Date: April 6, 2009

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

### Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, DME Medicare Administrative Contractors (DME MACs), Fiscal Intermediaries (FIs), A/B Medicare Administrative Contractors (A/B MACs), and/or Regional Home Health Intermediaries (RHHIs)) for services provided to Medicare beneficiaries.

### Provider Action Needed

This article is based on Change Request (CR) 6380 which informs Medicare contractors that on or after December 16, 2008, the January 2009 Average Sales Price (ASP) file will be available for download along with revisions to prior ASP payment files, if CMS determines that revisions to these prior files are necessary. In addition, on or after March 16, 2009, the April 2009 ASP NOC files will be available for retrieval from the Centers for Medicare & Medicaid Services (CMS)

#### Disclaimer

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ASP webpage along with revisions to prior ASP NOC files, if CMS determines that revisions to these prior files are necessary.

## Background

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The Medicare Modernization Act of 2003 (Section 303(c); see <http://www.cms.hhs.gov/MMAUpdate/downloads/PL108-173summary.pdf> on the CMS website) 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 your local Medicare contractor.

CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by the Social Security Act (Section 1847A; see [http://www.ssa.gov/OP\\_Home/ssact/title18/1847.htm](http://www.ssa.gov/OP_Home/ssact/title18/1847.htm) on the internet). As part of this effort, CMS has also reviewed how the terms "single source drug," "multiple source drug," and "biological product" have been operationalized 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. Specifically, CMS considers:

- 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) first sold in the United States after October 1, 2003, 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.

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 "not otherwise classified, (NOC)" HCPCS codes.

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### *ASP Methodology*

The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS supplies Medicare contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. Note that payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Integrated Outpatient Code Editor (I/OCE) through separate instructions.

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 will update these payment allowance limits quarterly.

Exceptions to this general rule as summarized below.

- 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 Ambulatory Payment Classification (APC) to which the product is assigned.
- 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 were not 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

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published AWP unless the drug is compounded or the drug is furnished incident to a professional service.

- 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.
- 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 the Medicare Claims Processing Manual, 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.

**Note:** *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 website.*

- 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

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WAC is not published, except under OPPTS 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. Your Medicare contractor, at their discretion, 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.

- The payment allowance limits for radiopharmaceuticals are not subject to the ASP payment methodology. Medicare contractors will 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.

### *Quarterly Payment Files*

On or after March 16, 2009, the April 2009 ASP NOC files will be available for retrieval from the CMS ASP webpage along with revisions to prior ASP NOC files, if CMS determines that revisions to these prior files are necessary. The payment files will be applied to claims processed or reprocessed on or after the effective date of CR 6380 (April 1, 2009) for the dates of service noted in the table that follows.

Please be aware that your Medicare contractor will not search and adjust claims that have already been processed unless you bring them to their attention.

Payment Allowance Limit Revision Date	Applicable Dates of Service
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
April 2008 ASP and ASP NOC files	April 1, 2008, through June 30, 2008

***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 will make these determinations*

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

Physicians (or a practitioner described in the Social Security Act (Section 1842(b) (18) (C); see [http://www.ssa.gov/OP\\_Home/ssact/title18/1842.htm](http://www.ssa.gov/OP_Home/ssact/title18/1842.htm) on the Internet) 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. 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.

### **Additional Information**

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The official instruction, CR 6380, issued to your carrier, FI, A/B MAC, RHHI, and DME MAC regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R1685CP.pdf> on the CMS website.

If you have any questions, please contact your carrier, FI, A/B MAC, RHHI, or DME MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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