

# MLN Matters®

Information for Medicare Fee-For-Service Health Care Professionals



**News Flash - An Overview of Medicare Preventive Services for Physicians, Providers, Suppliers, and Other Health Care Professionals** educational video program, provides information on Medicare-covered preventive services, risk factors associated with various preventable diseases, and highlights the importance of prevention, detection, and early treatment of disease. The program is an excellent resource to help physicians, providers, suppliers, and other health care professionals learn more about preventive benefits covered by Medicare. Running approximately 75 minutes in length, the program is suitable for individual viewing or for use in conjunction with a conference or training session. To order your copy today, go to the Medicare Learning Network Product Ordering page at [http://cms.meridianksi.com/kc/pfs/pfs\\_Inkfrm\\_fl.asp?lqfrm=regprod&function=pfs](http://cms.meridianksi.com/kc/pfs/pfs_Inkfrm_fl.asp?lqfrm=regprod&function=pfs) on the CMS website. Available in DVD or VHS format.

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Related Change Request (CR) #: 5646

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Implementation Date: July 2, 2007

## **July 2007 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File, Effective July 1, 2007, and Revisions to January 2007 and April 2007 Quarterly ASP Medicare Part B Drug Pricing Files**

**Note:** This article was updated on September 10, 2012, to reflect current Web addresses. This article was also revised on June 25, 2007, to delete references in the title and elsewhere to a revised October 2006 ASP file. All other information is the same.

### **Provider Types Affected**

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

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## Provider Action Needed

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This article is based on Change Request (CR) 5646 which informs Medicare providers of the availability of the July 2007 Average Sales Price (ASP) drug pricing file for Medicare Part B drugs as well as the revised January 2007 and April 2007 ASP files. Providers should make certain that your billing staffs are aware of these changes.

## Background

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The Medicare Modernization Act of 2003 (MMA; Section 303(c)) revised the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. Starting January 1, 2005, many of the drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) methodology, and pricing for compounded drugs is performed by the local Medicare contractor. Additionally, beginning 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 OPDS, will be paid based on the ASP methodology.

The ASP methodology is based on quarterly data submitted to the Centers for Medicare & Medicaid Services (CMS) by manufacturers, and CMS supplies Medicare contractors (carriers, DMERCs, DME MACs, FIs, A/B MACs, and/or RHHIs) with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. CMS also posts these files to its website at

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html> on the CMS website.

As announced in late 2006, after carefully examining Section 1847A of the Social Security Act, as added by the Medicare Modernization Act of 2003, CMS has been working further to ensure that more accurate and, as appropriate, separate payment is made for single source drugs and biologicals under Section 1847A. As part of this effort, CMS reviewed how the terms "single source drug," "multiple source drug," and "biological product" are 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. CMS 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

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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 under Section 1847A for that biological product or single source drug will be based on the pricing information for products produced or distributed under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may also be operationalized through use of existing specific HCPCS codes or "not otherwise classified" HCPCS codes.

**For 2007, a separate fee of \$0.152 per International Unit (I.U.) of blood clotting factor furnished is payable when a separate payment for the blood clotting factor is made. The furnishing fee will be included in the payment amounts on the quarterly ASP pricing files.**

### *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 (106%) of the ASP. Beginning January 1, 2006, payment allowance limits are paid based on 106 percent (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 OPPS.

Exceptions are summarized as follows:

- The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a prospective payment basis are 95 percent (95%) 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.
- 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 (95%) 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 2007.** Payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment (DME) that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent (95%) of the first published AWP unless the drug is compounded.

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- 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 and, then, 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 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. 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.
- 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 OPSS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs that were first sold on or after January 1, 2005.
- The payment allowance limits for radiopharmaceuticals are not subject to ASP. Medicare contractors determine payment limits for radiopharmaceuticals based on the methodology in place in 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 19, 2007, revised January 2007 and April 2007 ASP payment files and the July 2007 ASP file will be available for retrieval from the CMS ASP webpage. 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. The CMS ASP webpage is located at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html> on the CMS website.

The revised files are applicable to claims based on dates of service as shown in the following table:

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Payment Allowance Limit Revision Date	Applicable Dates of Service
July 2007	July 1, 2007, through September 30, 2007
January 2007	January 1, 2007, through March 31, 2007
April 2007	April 1, 2007, through June 30, 2007

**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 the Social Security Act (Section 1842(b) (18) (C); [http://www.ssa.gov/OP\\_Home/ssact/title18/1842.htm](http://www.ssa.gov/OP_Home/ssact/title18/1842.htm)) 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. Note that pricing for compounded drugs is done by your local Medicare contractor.

## Additional Information

The official instruction (CR5646) issued to your Medicare Carrier, FI, A/B MAC, DME MAC, or RHHI is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1270CP.pdf> on the CMS website.

If you have questions, please contact your Medicare carrier, FI or A/B MAC, DME MAC, or RHHI at their toll-free number which may be found at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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