



News Flash – The May 2007 version of the *Quick Reference Information: Medicare Preventive Services* laminated chart is now available to order or download from the Medicare Learning Network. To order, go to the “MLN Product Ordering Page” located at http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5 or to view online, go to http://www.cms.hhs.gov/MLNProducts/downloads/MPS_QuickReferenceChart_1.pdf on the CMS Website.

MLN Matters Number: MM5710

Related Change Request (CR) #: 5710

Related CR Release Date: September 12, 2007

Effective Date: October 1, 2007

Related CR Transmittal #: R1334CP

Implementation Date: October 1, 2007

Quarterly October 2007 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, Durable Medical Equipment 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

Provider Action Needed

This article is based on Change Request (CR) 5710, which informs Medicare providers of the availability of the October 2007 Average Sales Price (ASP) drug pricing file for Medicare Part B drugs as well as the revised January 2007, April 2007, July 2007 and October 2006 ASP payment files (**if CMS determines that revisions are necessary to the latter files**). CR5710 also advises Medicare providers that ASP Not Otherwise Classified (NOC) files will be available for retrieval from the CMS ASP webpage as well as the revised January 2007, April 2007, July 2007 and October 2006 ASP NOC files (**if CMS determines that**

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revisions are necessary to the latter files). Providers should make certain that your billing staffs are aware of these changes.

Background

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 Outpatient Prospective Payment System (OPPS), 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, 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.hhs.gov/McrPartBDrugAvgSalesPrice/> on the CMS website.

As announced in late 2006, 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 of the Social Security Act. As part of this effort, CMS reviewed how the terms "single source drug," "multiple source drug," and "biological product" are made operational 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 Food and Drug Administration (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 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

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payment may also be made operational 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 or the drug is furnished incident to a professional service. **The payment allowance limits were not 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 or the drug is furnished incident to a professional service.
- 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.

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- 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 FDA, are based on the published wholesale acquisition cost (WAC) or invoice pricing, except under OPPS 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 FDA 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 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 September 18, 2007, the October 2007 ASP file will be available for download from the CMS ASP website. If CMS determines that revisions are needed to the January 2007, April 2007, July 2007, and October 2006 ASP payment files, those revised files will also 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.hhs.gov/McrPartBDrugAvgSalesPrice/> on the CMS website. These quarterly 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 for Claims Processed or Reprocessed on or after October 1, 2007
October 2006	October 1, 2006 through December 31, 2006
January 2007	January 1, 2007 through March 31, 2007
April 2007	April 1, 2007 through June 30, 2007
July 2007	July 1, 2007 through September 30, 2007
October 2007	October 1, 2007 through December 31, 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 will 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) 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.

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Additional Information

To see the official instruction (CR5710) issued to your Medicare carrier, FI, A/B MAC, DME MAC, or RHHI. That instruction may be viewed by going to <http://www.cms.hhs.gov/Transmittals/downloads/R1334CP.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.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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