



News Flash -- The Medicare Learning Network's (MLN) Learning Management System (LMS) that hosts our web-based training courses and product ordering page will be unavailable for a period of approximately 7 to 10 days starting the week of September 22, 2008 while we perform system maintenance and upgrades. If you need MLN products or need to complete a web-based training course, it is recommended that you do so before September 17, 2008. Thank you for your interest in the Medicare Learning Network. If you have any questions, please send them to MLN@cms.hhs.gov.

MLN Matters Number: MM6175

Related Change Request (CR) #: 6175

Related CR Release Date: September 12, 2008

Effective Date: October 1, 2008

Related CR Transmittal #: R1595CP

Implementation Date: October 6, 2008

October 2008 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 (A/B 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

CR 6175, from which this article is taken, instructs Medicare contractors to download and implement the October 2008 Average Sales Price (ASP) drug pricing file for Medicare Part B drugs; and if released by the Centers for Medicare & Medicaid Services (CMS), also the revised July 2008, April 2008, January 2008, and October 2007 files.

Background

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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 average sales price (ASP) methodology, and pricing for compounded drugs has been performed by the local contractor.

The ASP methodology is based on quarterly data that drug manufacturers submit to CMS, which CMS then provides (quarterly) to Medicare contractors (carriers, DME MACs, FIs, A/B MACs, and/or RHHIs) through the ASP drug pricing files for Medicare Part B drugs. Please note that payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions.

As announced in late 2006, CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of the effort to ensure compliance with this requirement, 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 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), first sold in the United States after October 1, 2003; 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 "not otherwise classified, (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

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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 based on 105 percent of the ASP. Drugs and biologicals with pass-through status under the OPPS continue to have a payment allowance limit of 106 percent of the ASP. CMS will update the payment allowance limits quarterly.

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 determined in the same manner that 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 are 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 are not being 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 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 when the vaccine is furnished in a hospital outpatient department. When furnished in a 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 NOC Pricing File, other than new drugs and biologicals that are produced or distributed under a new drug

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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. In determining the payment limit based on WAC, Medicare 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.

Note: At their discretion, Medicare contractors may contact CMS to obtain payment limits for drugs and biologicals that are not included in the quarterly ASP or NOC files, or otherwise made available 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 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 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 and biologicals that were first sold on or after January 1, 2005.
- The payment allowance limits for radiopharmaceuticals are not subject to the ASP payment methodology. In the case of radiopharmaceuticals furnished in other than the hospital outpatient department, Medicare contractors determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003. 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 16, 2008, the October 2008 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. On or after September 16, 2008, the October 2008 ASP NOC files will be available for

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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 implementation date of CR6049 for the dates of service noted in the following table:

Payment Allowance Limit Revision Date	Applicable Dates of Service
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
January 2008 ASP and ASP NOC files	January 1, 2008, through March 31, 2008
October 2007 ASP and ASP NOC files	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 makes these determinations

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

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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.

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

Additional Information

You can find the official instruction, CR6175, issued to your carrier, FI, RHHI, A/B MAC, or DME MAC by visiting

<http://www.cms.hhs.gov/Transmittals/downloads/R1595CP.pdf> on the CMS website

If you have any 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.

News Flash - Flu Shot Reminder - Flu Season Is Coming! It's not too early to start vaccinating as soon as you receive vaccine. Encourage your patients to get a flu shot as it is still their best defense against the influenza virus. (*Medicare provides coverage of the flu vaccine without any out-of-pocket costs to the Medicare patient. No deductible or copayment/coinsurance applies.*) And don't forget, health care workers also need to protect themselves. **Get Your Flu Shot. – Not the Flu. Remember** - Influenza vaccine plus its administration are covered Part B benefits. Note that influenza vaccine is NOT a Part D covered drug. For information about Medicare's coverage of the influenza virus vaccine and its administration as well as related educational resources for health care professions and their staff, visit http://www.cms.hhs.gov/MLNProducts/Downloads/flu_products.pdf on the CMS website. To order, free of charge, a quick reference chart on Medicare Part B Immunization Billing, go to http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_id=kc0001&loc=5 on the CMS website.

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