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MLN Matters Number: MM6049

Related Change Request (CR) #: 6049

Related CR Release Date: June 6, 2008

Effective Date: July 1, 2008

Related CR Transmittal #: R1529CP

Implementation Date: July 7, 2008

July 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 6049, from which this article is taken, instructs Medicare contractors to download and implement the July 2008 Average Sales Price (ASP) drug pricing file for Medicare Part B drugs; and if released by CMS, also the revised April 2008, January 2008, January 2007, April 2007, July 2007, and October 2007 files.

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Background

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.

Additionally, beginning in 2006, all end-stage renal disease (ESRD) drugs (that both independent and hospital-based ESRD facilities furnish), as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), are paid based on the ASP methodology.

The ASP methodology is based on quarterly data that drug manufacturers submit to the Centers for Medicare & Medicaid Services (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.

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 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.

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As appropriate, a unique 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

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 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.

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 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 Class (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.

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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. 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 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 FDA, 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.**
- 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 OPSS 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. Medicare contractors 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.

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On or after June 16, 2008, the July 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 June 16, 2008, the July 2008 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 limits included in revised ASP and NOC payment files supersede the payment limits for these codes in any publication published prior to this document.

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
July 2008 ASP and ASP 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
July 2007 ASP and ASP NOC files	July 1, 2007, through September 30, 2007
April 2007 ASP and ASP NOC files	April 1, 2007, through June 30, 2007
January 2007 ASP and ASP NOC files	January 1, 2007, through March 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.

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Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir

Physicians 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

To see the official instruction (CR6049) issued to your Medicare contractor visit <http://www.cms.hhs.gov/Transmittals/downloads/R1529CP.pdf> on the CMS website.

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.

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