Medicare Learning Network
MLN Matters®
CMS
Information for Medicare Fee-For-Service Health Care Professionals

Flu Shot Reminder

As a respected source of health care information, patients trust their doctors' recommendations. If you have Medicare patients who haven't yet received their flu shot, help protect them by recommending an annual influenza and a one time pneumococcal vaccination. Medicare provides coverage for flu and pneumococcal vaccines and their administration. – And don't forget to immunize yourself and your staff. **Protect yourself, your patients, and your family and friends.** Get Your Flu Shot. Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. For more information about Medicare's coverage of adult immunizations and educational resources, go to *http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/SE0667.pdf* on the CMS website.

MLN Matters Number: MM5413 | Related Change Request (CR) #: 5413

Related CR Release Date: December 15, 2006 | Effective Date: January 1, 2007

Related CR Transmittal #: R1129CP | Implementation Date: January 2, 2007

Note: This article was updated on October 31, 2012, to reflect current Web addresses. All other information remains unchanged.

January 2007 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File, Effective January 1, 2007, and Revisions to April 2006, July 2006 and October 2006 Quarterly ASP Medicare Part B Drug Pricing Files

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.

Provider Action Needed

This article is based on Change Request (CR) 5413 which informs Medicare contractors to download the January 2007 Average Sales Price (ASP) drug pricing file for Medicare Part B drugs as well as the revised January 2006, April 2006, July 2006, and October 2006 files.

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 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, 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.

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 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 (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.
- Payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent (95%) 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 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 approved by the Food and Drug Administration, are based on the published wholesale acquisition cost (WAC) or invoice pricing. In determining the payment limit based on WAC, the Medicare contractors follow the methodology specified in the *Medicare Claims Processing Manual* (Pub. 100-04, Chapter 17, Drugs and Biologicals) for calculating the AWP but substitute WAC for AWP. The payment limit is 100 percent (100%) 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 that are produced or distributed under a new drug application approved by the Food and Drug Administration (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 (106%) of the WAC or invoice pricing, if the WAC is not published. 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. 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 December 19, 2006, the revised April, July and October 2006 and January 2007 ASP file and ASP Not Otherwise Classified (NOC) files will be available for retrieval from the CMS ASP webpage, and 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 revised files are applicable to claims based on dates of service as shown in the following table:

Payment Allowance Limit Revision Date	Applicable Dates of Service
April 2006	April 1, 2006 through June 30, 2006.
July 2006	July 1, 2006 through September 30, 2006.
October 2006	October 1, 2006 through December 31, 2006.
January 2007	January 1, 2007 through March 31, 2007.

NOTE: The absence or presence of a Healthcare Common Procedure Coding System (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) 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.

Additional Information

For complete details, please see the official instruction issued to your carriers, DMERCs, DME MACs, FIs, A/B MACs, and/or RHHIs regarding this change. That instruction may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1129CP.pdf on the CMS website.

If you have any questions, please contact your carriers, DMERCs, DME MACs, FIs, A/B MACs, and/or RHHIs at their toll-free number, which may be found on the CMS website at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html.