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

News Flash - It's Not Too Late to Get the Flu Shot. We are in the midst of flu season and a flu vaccine is still the best way to prevent infection and the complications associated with the flu. But re-vaccination is necessary each year because flu viruses change each year. Please encourage your Medicare patients who haven't already done so to get their annual flu shot. – And don't forget to immunize yourself and your staff. Protect yourself, your patients, and your family and friends. Get Your Flu Shot – Not the Flu! Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. Health care professionals and their staff can learn more about Medicare's coverage of adult immunizations and related provider education resources, by reviewing Special Edition MLN Matters article SE0748 at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0748.pdf* on the CMS website."

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Implementation Date: January 7, 2008

January 2008 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

What You Need to Know

CR 5852, from which this article is taken, instructs Medicare contractors to download and implement the January 2008 Average Sales Price (ASP) drug pricing file for Medicare Part B drugs; and if released by CMS, also the revised January 2007, April 2007, July 2007, October 2007, April 2006, July 2006, and October 2006 files.

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 methodolo*gy* 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:

1. The FDA approval,
2. Therapeutic equivalents as determined by the FDA, and
3. 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 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 basis are 106% of the ASP. Beginning January 1, 2006, payment allowance limits are paid based on the ASP methodology 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.

Summary of Exceptions to this General Rule

1. Except for blood clotting factors, the payment allowance limits for **blood and blood products** (that are not paid on a prospective payment basis) are determined in the same manner they were determined on October 1, 2003. Specifically, the payment allowance limits for blood and blood products are 95% of the average wholesale price (AWP) as reflected in the published compendia; and 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.

Note: 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 a new blood clotting factor when a new blood clotting factor is not included on the ASP file. For 2008, a separate fee of $0.158 per I.U. of blood clotting factor furnished is payable when 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.

2. Payment allowance limits for **infusion drugs furnished through a covered item of durable medical equipment** (DME) on or after January 1, 2005, will continue to be 95% of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or incident to a professional service. **The payment allowance limits will not be updated in 2008.**

Similarly, payment allowance limits for **infusion drugs furnished through a covered item of 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 furnished incident to a professional service.

3. The payment allowance limits for **influenza, Pneumococcal and Hepatitis B vaccines** are 95% of the AWP as reflected in the published compendia except, when administered in a hospital outpatient department, the vaccines are paid at reasonable cost.

4. Except for new drugs and biologicals that are produced, or distributed, under a new drug application (or other application) approved by the Food and Drug Administration (FDA), 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**, are based on the published wholesale acquisition cost (WAC) or invoice pricing (except under OPPS in which the payment allowance limit is 95% of the published AWP).

In determining the payment limit based on WAC, contractors will follow the methodology specified in the *Medicare Claims Processing Manual,* Chapter 17, Drugs and Biologicals, for calculating the AWP but will substitute WAC for AWP. The payment limit is 100% of the lesser of the lowest-priced brand or median generic WAC.

5. The payment allowance limits for **new drugs and biologicals** that were first sold on or after January 1, 2005; and are: 1) Produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration, and 2) Not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File; are based on 106% of the WAC (or invoice pricing if the WAC is not published) except under OPPS in which the payment allowance limit is 95% of the published AWP.

6. The payment allowance limits for **radiopharmaceuticals** are not subject to the ASP payment methodology. Contractors should 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.

7. The payment methodology for **drugs furnished incident to the filling or refilling of an implantable pump or reservoir** is determined under the ASP methodology (as described above) unless the drug furnished incident to the filling or refilling of an implantable pump or reservoir is a compounded drug, then pricing is performed by the local contractor.

Physicians (or a practitioner described in Section 1842(b) (18) (C)) may be paid for filling or refilling an implantable pump or reservoir when it is medically necessary that they 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.

On or after December 18, 2007, the January 2008 ASP file and ASP NOC files will be available for retrieval from the CMS ASP webpage. If CMS determines that revisions to the January 2007, April 2007, July 2007, October 2007, April 2006, July 2006 and October 2006 ASP payment files are necessary, the revised files will also be available for retrieval from the CMS webpage on or after December 18, 2007. The revised payment files will be applied to claims processed or reprocessed on or after this CR's (5852) effective date.

Table 1 below displays the payment allowance limit revision dates, and the applicable dates of service.

Table 1

Payment Allowance Limit Revision Date	Applicable Dates of Service
January 2008	January 1, 2008 through March 31, 2008
Revised January 2007*	January 1, 2007 through March 31, 2007
Revised April 2007*	April 1, 2007 through June 30, 2007;
Revised July 2007*	July 1, 2007, through September 30, 2007
Revised October 2007*	October 1, 2007 through December 31, 2007
Revised April 2006*	April 1, 2006 through June 30, 2006;
Revised July 2006*	July 1, 2006, through September 30, 2006
Revised October 2006*	October 1, 2006, through December 31, 2006

*If made available by CMS

Note: *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.*

Final Notes: 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.

Contractors (at their discretion) may contact CMS to obtain payment limits for drugs and biologicals not included in the quarterly ASP or NOC files, or that CMS has not otherwise made available on its website. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing.

Contractors will not search for, and adjust, a claim that has already been processed unless you bring it to their attention.

Implementation

The implementation date is January 7, 2008.

Additional Information

For complete details, please see the official instruction (CR 5852) issued to your carriers, DME MACs, FIs, A/B MACs, and/or RHHIs regarding this change, by visiting *http://www.cms.hhs.gov/Transmittals/downloads/R1406CP.pdf* on the CMS website.

If you have any questions, please contact your contractor at their toll-free number, which may be found at *http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip* on the CMS website.