

MLN Matters Number: MM4319

Related Change Request (CR) #: 4319

Related CR Release Date: February 24, 2006

Effective Date: April 1, 2006

Related CR Transmittal #: R876CP

Implementation Date: April 3, 2006

April 2006 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File and Revisions to January 2005, April 2005, July 2005, October 2005, and January 2006 Quarter ASP Medicare Part B Drug Pricing Files

Note: This article was revised to contain Web addresses that conform to the new CMS website and to show they are now MLN Matters articles. All other information remains the same.

Provider Types Affected

All Medicare providers who bill Medicare for Part B drugs

Provider Action Needed



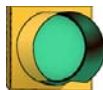
STOP – Impact to You

CR4319 provides notice of the updated payment allowance limits for Medicare Part B drugs, effective April 1, 2006 through June 30, 2006, as well as revised payment files for the January 2005, April 2005, July 2005, October 2005, and January 2006 Quarter ASP Medicare Part B Drug Pricing Files.



CAUTION – What You Need to Know

Be aware that certain Medicare Part B drug payment limits have been revised and that the Centers for Medicare & Medicaid Services (CMS) updates the payment allowance quarterly. The revised payment limits included in the revised ASP and Not Otherwise Classified (NOC) payment files supersede the payment limits for these codes in any publication published prior to CR4319.



GO – What You Need to Do

Make certain that your billing staffs are aware of these changes.

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Background

According to Section 303 (c) of the Medicare Modernization Act of 2003 (MMA), CMS will update the payment allowances for Medicare Part B drugs on a quarterly basis.

Beginning January 1, 2005, Part B drugs that are not paid on a cost or prospective payment basis) are paid based on **106 percent** of the average sales price (ASP).

Additionally, 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 OPPTS, will be paid based on the ASP methodology. The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply Medicare contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis.

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.

Beginning January 1, 2006, the payment allowance limits for all ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPTS, will be paid based on 106 percent of the ASP. CMS will update the payment allowance limits quarterly.

Exceptions to General Rule

There are exceptions to this general rule as summarized below:

Blood and Blood Products

For blood and blood products (with certain exceptions such as blood clotting factors), payment allowance limits are determined in the same manner they were determined on October 1, 2003.

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 will be updated on a quarterly basis.

Infusion Drugs

For infusion drugs furnished through a covered item of Durable Medical Equipment (DME) on or after January 1, 2005, payment allowance limits will continue to be 95 percent of the AWP reflected in the published compendia as of October 1, 2003, regardless of whether or not the DME is implanted.

The payment allowance limits were not updated in 2005. 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), the payment allowance limits are 95 percent of the first published AWP.

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Influenza, Pneumococcal, Hepatitis B Vaccines

For influenza, pneumococcal, and hepatitis B vaccines, payment allowance limits are 95 percent of the AWP as reflected in the published compendia.

Drugs Not Included in ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File

For drugs (other than new drugs) not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, payment allowance limits are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing.

In determining the WAC-based payment limit, Medicare contractors (carriers, including durable medical equipment regional carriers (DMERCs), and fiscal intermediaries, including regional home health intermediaries (RHHIs)) will follow the methodology specified in the *Medicare Claims Processing Manual* for calculating the AWP, but substitute WAC for AWP. (See Publication 100-04, Chapter 17, Drugs and Biologicals) at

<http://www.cms.hhs.gov/manuals/downloads/clm104c17.pdf> on the CMS website. The payment limit is 100 percent of the lesser of the lowest brand or median generic WAC.

Your Medicare contractor may, at their discretion, contact CMS to obtain payment limits for drugs not included in the quarterly ASP or NOC files. If available, CMS will provide the payment limits either directly to the requesting contractor or will post them in an MS Excel file on the CMS web site. If the payment limit is available from CMS, contractors will substitute the CMS-provided payment limits for pricing based on WAC or invoice pricing.

Radiopharmaceuticals

The payment allowance limits for **radiopharmaceuticals** are not subject to ASP. Your carrier/FI will determine payment limits for radiopharmaceuticals based on the methodology in place as of November, 2003.

New Drugs Produced or Distributed under a New Drug Application Approved by the Food and Drug Administration

The payment allowance limits for new drugs and biologicals 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. This policy applies only to new drugs that were first sold on or after January 1, 2005.

How the ASP is Calculated

The ASP is calculated using data submitted to CMS by manufacturers on a quarterly basis and each quarter, CMS will update your carrier payment allowance limits with the ASP files. On or after March 20, 2006, revised January 2005, April 2005, July 2005, October 2005, and January 2006 ASP and NOC payment files and the April 2006 ASP and NOC files will be available for download.

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- The revised January 2005 payment allowance limits apply to dates of service January 1, 2005 through March 31, 2005.
- The revised April 2005 payment allowance limits apply to dates of service April 1, 2005 through June 30, 2005.
- The revised July 2005 payment allowance limits apply to dates of service July 1, 2005 through September 30, 2005.
- The revised October 2005 payment allowance limits apply to dates of service October 1, 2005 through December 31, 2005.
- The revised January 2006 payment allowance limits apply to dates of service January 1, 2006 through March 31, 2006.
- The April 2006 payment allowance limits apply to dates of service April 1, 2006 through June 30, 2006.

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 carrier processing your claim will make these determinations.

For any drug or biological not listed in the ASP or NOC drug pricing files, your Medicare contractor will determine the payment allowance limits in accordance with the policies described in CR4319 and fiscal intermediaries will seek payment allowances from the local Medicare carrier.

Implementation

The implementation date for the instruction is April 3, 2006

Additional Information

The official instructions issued to your carrier/FI/RHHI/DMERC regarding this change can be found at <http://www.cms.hhs.gov/Transmittals/downloads/R876CP.pdf> on the CMS website.

If you have questions, please contact your Medicare carrier/FI/RHHI/DMERC at their toll-free number which may be found at: <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

More information is available at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/> on the CMS website.

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