



News Flash - The Medicare Appeals Process: Five Levels to Protect Providers, Physicians and Other Suppliers brochure has been updated and is now available to order print copies or as a downloadable PDF file. To view the PDF file, go to <http://www.cms.hhs.gov/MLNProducts/downloads/MedicareAppealsProcess.pdf> or to order hard copies, please visit the MLN Product Ordering Page at http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5 on the CMS website.

MLN Matters Number: MM5798

Related Change Request (CR) #: 5798

Related CR Release Date: May 23, 2008

Effective Date: June 23, 2008

Related CR Transmittal #: R1513CP

Implementation Date: June 23, 2008

Average Sales Price (ASP) Updates

Provider Types Affected

Physicians, providers, and suppliers who submit claims to Medicare contractors (carriers, fiscal intermediaries (FIs), Part A/B Medicare Administrative Contractors (A/B MACs), and DME Medicare Administrative Contractors (DME MACs)) for services provided to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 5798 and provides you with updates and additions to language in the Medicare Claims Processing Manual relating to the ASP drug pricing and payment methodology. This article is informational to advise providers that the information is now in the Medicare manual and this information has been supplied in prior MLN Matters articles.

Key Points

The Centers for Medicare & Medicaid Services (CMS) provides an ASP file to each FI, carrier, DME MAC, and A/B MAC for pricing drugs. Each FI, carrier, DME

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MAC, and A/B MAC must accept the ASP files made available by CMS for pricing bills/claims for any drug identified on the price files as **these files are the single national payment limit** established by CMS.

- The payment limits included in the revised ASP and Not Otherwise Classified (NOC) payment files supersede the payment limits for these codes in any earlier publication.

ASP Payment Methodology

- The ASP methodology is based on quarterly data submitted to CMS by manufacturers and the updated and new guidelines established that relate to ASP pricing, payment methodology, and exceptions, are stated in Chapter 17, Section 20 of the *Medicare Claims Processing Manual* at <http://www.cms.hhs.gov/manuals/downloads/clm104c17.pdf> on the CMS website.
- 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. Your local Medicare contractor processing the claim will make these determinations.
- The vast majority of drugs and biologicals not priced on a cost or prospective payment basis will be priced based on the ASP methodology.
- Pricing for compounded drugs is done by your local contractor.
- End Stage Renal Disease (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 Outpatient Prospective Payment System (OPPS), will be priced based on the ASP methodology.
- 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.
- The payment allowance limits for 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 OPPS, will be paid based on 106 percent of the ASP.

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- For the purposes of identifying “single source drugs” and “biological products” subject to payment under Section 1847A, generally CMS (and its contractors) will utilize a multi-step process, in which CMS considers:
 1. The Food & Drug Administration (FDA) approval;
 2. Therapeutic equivalents as determined by the FDA; and
 3. The date of first sale in the United States.
- For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are 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, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment, which may be made operational through use of “not otherwise classified” HCPCS codes.

Exceptions to the ASP Payment Methodology

- The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a reasonable charge or 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 of the average wholesale price (AWP) as reflected in the published compendia.
- The 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 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 where the vaccine is furnished in a hospital outpatient department.

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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 Not Otherwise Classified (NOC) Pricing File, other than new drugs 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 OPPS 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, <http://www.cms.hhs.gov/manuals/downloads/clm104c17.pdf> on the CMS website, for calculating the AWP, but substitutes WAC for AWP. The payment limit is 100 percent of the lesser of the lowest-priced brand or median generic WAC.
- Carriers, DME MACs, and A/B MACs will develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing 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 Not Otherwise Classified (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.
- The payment allowance limits for radiopharmaceuticals are not subject to ASP. Carriers will 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. Please refer to Chapter 17, Section 90.2 of the *Medicare Claims Processing Manual* regarding radiopharmaceuticals furnished in the hospital outpatient department.

Additional Information

You may see the official instruction (CR5798) issued to your Medicare contractor by visiting <http://www.cms.hhs.gov/Transmittals/downloads/R1513CP.pdf> on the CMS website.

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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.

The ASP methodology files are posted at

<http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/> on the CMS website.

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