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MLN Matters Number: MM5270
Related Change Request (CR) #: 5270
Related CR Release Date: September 22, 2006
Effective Date: October 1, 2006
Related CR Transmittal #: R1066CP
Implementation Date: October 2, 2006

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

Note: This article was updated on November 6, 2012, to reflect current Web addresses. This article was previously revised on September 25, 2006, to reflect changes to CR5270, which CMS re-issued on September 22, 2006. The article was revised, as was CR5270, to remove references to the revised January 2006 file. The CR transmittal number, release date, and Web address for accessing CR5270 were also changed. 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

Change Request (CR) 5270, upon which this article is based, provides notice of the updated payment allowance limits effective October 1, 2006, and revisions to the April 2006 and July 2006 quarterly drug pricing files.

CAUTION – What You Need to Know

Be aware that certain Medicare Part B drug payment limits have been revised and that CMS updates the payment allowance on a quarterly basis. 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 this document.

GO – What You Need to Do

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

Background

CR5270, upon which this article is based, provides the quarterly average sales price (ASP) Medicare Part B drug pricing file update for October 1, 2006, and also provides revisions to the April 2006 and July 2006 quarterly files.

Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis; and mandated that since January 1, 2005, drugs and biologicals not paid on a cost or prospective payment basis be paid based on the average sales price (ASP) methodology.

In the same way in 2006, all ESRD drugs furnished by both independent and hospital-based ESRD facilities; specified, covered outpatient drugs; and drugs and biologicals with pass-through status under the OPPS will be paid according to this ASP methodology, which is based on quarterly data submitted to CMS by manufacturers.

Note that MMA also requires CMS to update the payment allowance limits quarterly, which CR5270 does.

Beginning January 1, 2005, Part B drugs that are not paid on a cost or prospective payment basis) have been paid based on 106% of the average sales price (ASP). Additionally, 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 OPPS, will be paid based on 106% of the ASP.

There are exceptions to this general rule as summarized below.

1. Blood and Blood Products

Blood and blood products furnished in the hospital outpatient department are paid under the outpatient prospective payment system (OPPS) at the amount specified for the APC to which the product is assigned. Conversely, for blood and blood products, not paid on a prospective payment basis (with certain exceptions such as blood clotting factors), payment allowance limits are determined in the same manner used to determine them on October 1, 2003.

The payment allowance limits for blood and blood products are 95% of the Average Wholesale Price (AWP) as reflected in the published compendia. These payment allowance limits will be updated on a quarterly basis, along with the others.

2. Infusion Drugs

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% of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded. The payment allowance limits were not updated in 2006.

The payment allowance limits for infusion drugs (unless compounded), 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% of the first published AWP.

3. Influenza, Pneumococcal and Hepatitis B vaccines

The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95% of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. In this latter instance, the vaccine is paid at reasonable cost.

4. Drugs not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File

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, Medicare contractors (carriers, including durable medical equipment regional carriers (DMERCs), and fiscal intermediaries, including regional home health intermediaries (RHHIs)) follow the methodology in the *Medicare Claims Processing Manual* specified for calculating the AWP, but substitute WAC for AWP. (See Publication 100-04, Chapter 17, Drugs and Biologicals at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf on the CMS website.)

The payment limit is 100% of the lesser of the lowest brand or median generic WAC. And note that for 2006, when the blood clotting factor is not included on the ASP file, the blood clotting furnishing factor of $0.146 per I.U. is added to the blood clotting factor payment amount.

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.

1. New Drugs

The payment allowance limits for new drugs that are produced or distributed under a new drug application approved by the Food and Drug Administration 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% of the WAC. This policy applies only to new drugs that were first sold on or after January 1, 2005. As mentioned above, for 2006, the blood clotting furnishing factor of $0.146 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.

2. Radiopharmaceuticals

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. And your carrier/FI will determine payment limits for radiopharmaceuticals not furnished in the hospital outpatient department based on the methodology in place as of November 2003.

3. Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir

CR 5270 clarifies that 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. Your carrier or FI will develop the pricing for compounded drugs.

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 for them to perform the service. Your carrier/FI must find the use of the implantable pump or reservoir medically reasonable and necessary in order to allow payment for: 1) The professional service of filling or refilling the implantable pump or reservoir; and 2) 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: 1) The medication administered is accepted as a safe and effective treatment of the patient's illness or injury; 2) There is a medical reason that the medication cannot be taken orally; and 3) The nurse's skills are needed to infuse the medication safely and effectively.

Here are some important things you should remember.

- 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.
- Pricing for compounded drugs is performed by your carrier/FI.
- The presence or absence or 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.
- The October 2006 and revised April 2006 and July 2006 ASP drug pricing files for Medicare Part B drugs will be available via the CMS Data Center (CDC) for your carriers/FIs to download on or after September 19, 2006.
- You can also view the October 2006 and revised April 2006, and July 2006 ASP NOC drug pricing files for Medicare Part B drugs (on or after September 22, 2006) at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html on the CMS website.

Note that:

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

Additional Information

You can find the official instructions issued to your carrier/FI/RHHI/DMERC *regarding this change by going to CR5270, located at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1066CP.pdf *on the CMS website. If you have any questions, please contact your carrier at their toll-free number, which may be found at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html *on the CMS website.*