

Medicare contractors will reject line items that are not related to the clinical trial and, therefore, not payable under FFS for managed care enrollees. Contractors will use the following messages when line-item rejecting:

Medicare Summary Notice:

11.1 - Our records show that you are enrolled in a Medicare health plan. Your provider must bill this service to the plan.

Claim Adjustment Reason Code:

24 - Charges are covered under a capitation agreement/managed care plan.

Group Code:

CO – Contractual Obligation

Additional Information

If you have questions, please contact your Medicare FI and/or MAC at their toll-free number which may be found at

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS Website. The official instruction, CR6455, issued to your Medicare FI and/or MAC regarding this change may be viewed at

<http://www.cms.hhs.gov/Transmittals/downloads/R1723CP.pdf> on the CMS Website.

**JULY 2009 QUARTERLY AVERAGE SALES PRICE (ASP) MEDICARE
PART B DRUG PRICING FILES AND REVISIONS TO PRIOR
QUARTERLY PRICING FILES**

~CMS MLN Matters~

MLN Matters Number: MM6471

Related CR Release Date: May 15, 2009

Related CR Transmittal #: R1737

Related Change Request (CR) #: 6471

Effective Date: July 1, 2009

Implementation Date: July 6, 2009

Provider Types Affected

All physicians, providers and suppliers who submit claims to Medicare contractors (Medicare Administrative Contractors (MACs), Fiscal Intermediaries (FIs), carriers, Durable Medical Equipment Medicare Administrative Contractors (DME MACs) or Regional Home Health Intermediaries (RHHIs)) for services provided to Medicare beneficiaries.

What You Need to Know

This article is based on Change Request (CR) 6471 and instructs Medicare contractors to download and implement the July 2009 ASP drug pricing file for Medicare Part B drugs; and if released by the Centers for Medicare & Medicaid Services (CMS), also the revised April 2009, January 2009, October 2008 and July 2008, files. They will use the July 2009 ASP and not otherwise classified (NOC) drug pricing files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 6, 2009 with dates of service July 1, 2009, through September 30, 2009.

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 ASP methodology, and pricing for compounded drugs has been performed by the local contractor.

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:

- The Food and Drug Administration (FDA) approval;
- Therapeutic equivalents as determined by the FDA; and
- 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), 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 Healthcare Common Procedure Coding System (HCPCS) code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of 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 percent of the ASP. Further, beginning January 1, 2006, payment allowance limits are paid based on 106 percent of the ASP for:

- End Stage Renal Disease (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 OPSS.

Beginning January 1, 2008, under the OPSS, payment allowance limits for specified covered outpatient drugs are paid at ASP+5%. Beginning January 1, 2009, under the OPSS, payment allowance limits for specified covered outpatient drugs are paid at ASP+4%. Drugs and biologicals with pass-through status under the OPSS continue to have a payment allowance limit of 106% of the ASP. CMS will update the payment allowance limits quarterly. There are exceptions to this general rule and they are stated in the Medicare Claims Processing Manual, Chapter 17, Section 20.1.3 and may be reviewed at <http://www.cms.hhs.gov/manuals/downloads/clm104c17.pdf> on the CMS Website.

Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir

Physicians (or a practitioner described in Section 1842(b) (18) (C) of the Social Security Act) 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.

Medicare 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, except that pricing for compounded drugs is done by your local Medicare contractor.

Use of Quarterly Payment Files

The following table shows how the quarterly payment files will be applied:

Payment Allowance Limit Revision Date	Applicable Dates of Service
July 2009 ASP and ASP NOC file	July 1, 2009, through September 30, 2009
April 2009 ASP and ASP NOC files	April 1, 2009, through June 30, 2009
January 2009 ASP and NOC Files	January 1, 2009, through March 31, 2009
October 2008 ASP and NOC Files	October 1, 2008, through December 31, 2008
July 2008 ASP and NOC files	July 1, 2008, through September 30, 2008

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 local Medicare contractor processing the claim makes these determinations

Additional Information

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 official instruction (CR6471) issued to your Medicare carrier, FI, RHHI, MAC, or DME MAC is available at <http://www.cms.hhs.gov/Transmittals/downloads/R1737CP.pdf> on the CMS Website.

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Part A Legacy	
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