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MMA-Hospital Outpatient Billing and Payment under Outpatient Prospective Payment System for New Drugs or Biologicals After FDA Approval but Before Assignment of a Product-Specific Drug/Biological HCPCS Code

Note: This article was updated on May 9, 2013, to reflect current Web addresses. All other information remains unchanged.

Provider Types Affected

Providers who bill under the Outpatient Prospective Payment System (OPPS)

Impact on Providers

Providers should note that beginning January 1, 2004, hospital outpatient departments may bill for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which pass-through status has not been approved, and a product-specific C-code and APC payment have not been assigned.

Background

Section 621 (a) of the Medicare Modernization Act (MMA) amends Section 1833 (t) of the Social Security Act by adding paragraph (15), "Payment for New Drugs and Biologicals Until HCPCS code are Assigned."

This provision applies only to payments under the OPPS. According to the provision, payment for an outpatient drug or biological that is furnished as part of covered outpatient department services, for which a product-specific Healthcare Common Procedure Coding System (HCPCS) code has not been assigned, shall be paid an amount equal to 95 per cent of the Average Wholesale Price (AWP).

Thus, for drugs/biologicals provided on or after January 1, 2004 that are approved by FDA on or after that date and for which pass-through status has not been approved and a product-specific C-code and APC payment have not been assigned, outpatient departments may bill for the drug as follows:

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- For drugs receiving FDA approval on or after January 1, 2004, hospitals may bill for the drug/biological using a new “unclassified code of C9399 (unclassified drug or biological).
- For the ANSI ASC X12N 837 I, hospital outpatient departments will report on TOB = 13x, containing revenue code 0636, HCPCS code C9399, and NDC number present in Loop 2400 LIN 03 of the 837 I. Alternatively, the hospital may report in the “Remarks” section of the CMS-1450 or its electronic equivalent (UB-92 flat file version 6.0), the National Drug Code (NDC) for the drug, the quantity of the drug that was administered, expressed in the unit of measure applicable to the drug or biological, and the date the drug was furnished to the beneficiary.

Medicare intermediaries will manually calculate the payment for the drug or biological at 95 per cent of the AWP. The intermediary will pay 80 per cent of that calculated payment to the hospital; beneficiaries will be responsible for the 20 percent co-pay after the deductible is met.

Providers should note that drugs or biologicals that are manually priced under these instructions will not be eligible for outlier payment. Also, the fact that CMS establishes a code and sets a payment rate for a drug or biological does not imply coverage by the Medicare program, but indicates only how the drug or biological may be paid if covered by the program. Fiscal intermediaries determine whether a drug or biological meets all program requirements for coverage, for example, that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

Also, beginning January 1, 2004, CMS will assign a drug/biological, product-specific HCPCS C-code and APC payment to a drug or biological approved by the FDA after January 1, 2004 that is approved for pass-through status. The process to apply for pass-through status for a drug or biological is explained on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/drugapplication.pdf> on the CMS website.

C-codes and APC payments for drugs and biologicals approved for pass-through status are implemented prospectively beginning in July 2004.

CMS will issue further instructions in the future regarding billing and payment under the 2005 OPSS for drugs and biologicals approved by the FDA after January 1, 2004 for which a product-specific C code has been assigned.

Additional Information

For further information, see the instruction issued to your intermediary regarding this issue, which can be found by going to <http://www.cms.gov/Regulations->

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[and-Guidance/Guidance/Transmittals/downloads/R188CP.pdf](#) on the CMS website.

If you have questions, please contact your intermediary 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.

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