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MLN Matters



Information for Medicare Fee-for-Service Health Care Professionals



Do you have your NPI? National Provider Identifiers (NPIs) will be required on claims sent on or after May 23, 2007. Every health care provider needs to get an NPI. Learn more about the NPI and how to apply for an NPI by visiting <http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/index.html> on the CMS website.

MLN Matters Number: MM5259

Related Change Request (CR) #: CR5259

Related CR Release Date: August 18, 2006

Effective Date: January 1, 2007

Related CR Transmittal #: R1034CP

Implementation Date: January 2, 2007

Competitive Acquisition Program (CAP) – Claim Processing for Not Otherwise Classified (“NOC”) Drugs

Note: This article was updated on November 9, 2012, to reflect current Web addresses. This article was previously revised on January 29, 2007, to alert participating physicians that the dose of the drug should be coded also in item 19 of paper claims or Loop 2300 segment NTE on electronic claims. All other information remains the same.

Provider Types Affected

Physicians participating in the Medicare Part B Drug CAP.

Impact on Providers

This article is based on Change Request (CR) 5259, which describes the process for adding Not Otherwise Classified (NOC) Drugs to the CAP beginning in 2007. It provides additional details, information and instructions for the implementation of the CAP as outlined previously in CRs 4064, 4306, 4309 and 5079 and the *MLN Matters* articles related to those CRs.

Background

As discussed in the November 21, 2005 CAP final rule (http://www.access.gpo.gov/su_docs/fedreg/a051121c.html) and in response to public comments about beneficiary access to new medications, CMS provided for the addition of NOC drugs to the CAP beginning in 2007. CMS believes that the addition of NOC drugs to the CAP will improve beneficiaries' access to newly marketed drugs that have a national sales price, will decrease the reliance on buy

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and bill acquisition and will further simplify the drug acquisition process for physicians who have elected to participate in the CAP.

PROCESS TO ADD NOC DRUGS TO A CAP VENDOR'S DRUG LIST

The process for adding NOC drugs to the CAP will basically follow the process for adding other drugs to the CAP as described in CR5079. An approved CAP vendor will be required to submit a written request to add specific NOC drugs to the CAP designated carrier. The request must include:

- A rationale for the proposed change,
- A discussion of the impact on the CAP (including safety, waste, etc.), and
- The potential for cost savings.

CMS will define a list of CAP NOC drugs that the approved CAP vendor must use when requesting the addition of NOC drugs to the CAP. The CAP NOC drug list will be based on the ASP NOC list, but will include only drugs that are both likely to fit the existing CAP drug category (or categories) and drugs that have a single national ASP-based payment amount. The CAP NOC drug list will be posted on the CMS CAP website and updated quarterly.

If approved, changes will become effective at the beginning of the following quarter. CMS will post the changes on the CMS website (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html>) and notify the carriers and participating CAP physicians of any changes on a quarterly basis. Participating CAP physicians will be notified of changes to their approved CAP vendor's CAP drug list on a quarterly basis and at least 30 days before the approved changes are due to take effect. CAP drug list approvals apply only to the CAP vendor who submitted the request and to the category identified on the request. Therefore, each vendor's drug list may contain different drugs after changes to the initial drug list are approved. The CAP NOC drug payment amount will be at the same rate as published on the ASP NOC file consistent with the next quarterly update, and the payment amount will be updated annually as for other CAP drugs.

CAP NOC CLAIMS SUBMISSION REQUIREMENTS

CMS requires the use of a CAP-specific Q code (Q4082 Drug/bio NOC part B drug CAP) for CAP NOC drug claims in order to distinguish CAP NOC drug claims from ASP NOC claims and to prevent the CAP claims from being paid outside the Medicare Part B drug CAP. Physician drug administration claims for CAP NOC drugs are required to

- use the CAP-specific NOC Q-code: Q4082 Drug/bio NOC part B drug CAP
- and identify the specific NOC drug and dose that had been administered in Item 19 on paper claims or Loop 2300 Segment NTE on electronic claims

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- Physician claims must also contain the appropriate CAP modifiers (J1, J2, J3)
All other CAP claim parameters will remain the same

Note: Physicians who have elected to participate in the CAP should continue to use ASP NOC codes when billing for NOC drugs that are outside the CAP. Also remember that physicians who participate in the CAP are required to obtain all CAP drugs on the updates from the approved CAP vendor unless medical necessity requires the use of a formulation not supplied by the vendor.

RETURNED CAP NOC CLAIMS

For the following three situations, if:

- The claim is submitted with a CAP NOC code, but the description does not match a CAP NOC drug on the approved list; or
- The claim is submitted with a CAP NOC code by a non-CAP physician; or
- The claim is submitted with a J NOC code with a description of a CAP approved NOC drug.

Then:

- Claims will be returned to physicians with a reason code of 16 (Claim/service lacks information needed for adjudication) and remark code MA 130 (Your claims contain incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable).
- Remark code N350 (Missing/incomplete/invalid description of a service for a NOC code or unlisted procedure) will also appear in the first situation.
- Remark code N56 (Procedure code billed is not correct/valid for the services billed or the date of service billed) will appear in the second and third situations.

Additional Information

Section 303 (d) of the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003, requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals ("drugs") not paid on a cost or prospective payment system basis. Beginning with drugs administered on or after July 1, 2006, physicians will be given a choice between buying and billing these drugs under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. A participating CAP physician will submit a claim for drug administration to the Medicare local carrier. An approved CAP vendor will submit a claim for the drug product to the CAP Medicare designated carrier.

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Change Request (CR) 5259 is not a stand-alone CR. It provides additional details, information, and instructions for the implementation of the Competitive Acquisition Program (CAP) as outlined in:

- CR4064 (<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R777CP.pdf>; <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM4064.pdf>),
- CR4306 (<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R841CP.pdf>),
- CR4309 (<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R866CP.pdf>; <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM4309.pdf>) and
- CR 5079 (<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1055CP.pdf>; <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM5079.pdf>).

For complete details, please see the official instruction issued to your carrier regarding this change. That instruction may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1034CP.pdf> on the CMS website.

If you have any questions, please contact your carrier at their toll-free number, which may be found on the CMS website at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

Flu Shot Reminder As a respected source of health care information, patients trust their doctors' recommendations. If you have Medicare patients who haven't yet received their flu shot, help protect them by recommending an annual influenza and a one time pneumococcal vaccination. Medicare provides coverage for flu and pneumococcal vaccines and their administration. – And don't forget to immunize yourself and your staff. **Protect yourself, your patients, and your family and friends.** Get Your Flu Shot. Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. For more information about Medicare's coverage of adult immunizations and educational resources, go to CMS's website: <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/SE0667.pdf> on the CMS website.

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