



News Flash – Test Your Medicare Claims Now! After you have submitted claims containing both National Provider Identifiers (NPIs) and legacy identifiers and those claims have been paid, Medicare urges you to send a small batch of claims now with only the NPI in the primary provider fields. If the results are positive, begin increasing the number of claims in the batch. (Reminder: For institutional claims, the primary provider fields are the Billing and Pay-to Provider fields. For professional claims, the primary provider fields are the Billing, Pay-to, and Rendering Provider fields. If the Pay-to Provider is the same as the Billing Provider, the Pay-to Provider does not need to be identified.)

MLN Matters Number: MM5790

Related Change Request (CR) #: 5790

Related CR Release Date: January 18, 2008

Effective Date: April 1, 2008

Related CR Transmittal #: R3100TN

Implementation Date: April 7, 2008

Use of an 8-Digit Registry Number on Clinical Trial Claims

Provider Types Affected

Physicians, providers, and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FIs), Medicare Administrative Contractors (A/B MACs) and Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for services provided to Medicare beneficiaries in clinical research studies.

Provider Action Needed

This article is based on Change Request (CR) 5790 that notifies providers and suppliers that Medicare claims forms will be modified to accommodate the 8-digit clinical trial number for claims that Medicare receives on or after April 1, 2008. Reporting this number is voluntary and claims submitted without the clinical trial number will be paid the same as claims containing a number. While reporting is voluntary, the number will assist the Centers for Medicare & Medicaid Services (CMS) in informing beneficiaries about the availability of clinical trials and to use claims information to inform coverage decisions. Be sure your billing staff is aware of this rule.

Background

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2007 American Medical Association.

The purpose of CR5790 is to instruct providers and suppliers on new, voluntary reporting for placing a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination Manual, Publication 100-03, section 310.1. That publication is available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp> on the CMS website. The clinical trial number that the CMS is requesting to be voluntarily reported is the number assigned by the National Library of Medicine (NLM) Clinical Trials Data Bank when a new study is registered by a sponsor or investigator. Information regarding NLM clinical trials is available at <http://clinicaltrials.gov/> on the Internet.

CMS will use this number to identify all items and services provided to beneficiaries during their participation in a clinical trial. Furthermore, this identifier will permit CMS to meet the recommendations of the 2000 Institute of Medicine report that led to the Executive Memorandum to increase participation of Medicare beneficiaries in clinical trials and the development and implementation of the CMS clinical trials policy.

Recommendations from The White House Executive Memorandum included:

- Tracking Medicare payments;
- Ensuring that the information gained from the research is used to inform coverage decisions;
- Making certain that the research focuses on issues of importance to the Medicare population; and,
- Enabling CMS to better inform Medicare beneficiaries about the clinical studies available for their participation.

Key Points

- Claims submitted without the clinical trial number will be paid the same as claims containing a number.
- Institutional clinical trial claims are identified through the presence of all of the following elements:
 - Value Code D4 and corresponding 8-digit clinical trial number (when present on the claim);
 - ICD-9 diagnosis code V70.7;
 - Condition Code 30; and

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- HCPCS modifier Q1: outpatient claims only. (See MM5805 related to CR5805 for more information regarding modifier Q1.)
- Practitioner/DME clinical trial claims are identified through the presence of all of the following elements:
 - ICD-9 diagnosis code V70.7;
 - HCPCS modifier Q1; and
 - 8-digit clinical trial number (when present on the claim).
- On institutional claims, the 8-digit numeric clinical trial number should be placed in the value amount of value code D4 on the paper claim UB-40 (Form Locators 39-41) or in Loop 2300, HI – Value Information segment, qualifier BE on the 837I.
- On professional claims, the clinical trial registry number should be preceded by the two alpha characters of “CT” and placed in Field 19 of the paper Form CMS-1500 or it should be entered WITHOUT the “CT” prefix in the electronic 837P in Loop 2300 REF02(REF01=P4).

Additional Information

If you have questions, please contact your Medicare A/B MAC, FI, DME/MAC, or carrier at their toll-free number which may be found at:

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

You may see the official instruction (CR5790) issued to your Medicare A/B MAC, FI, DME/MAC, or carrier by going to

<http://www.cms.hhs.gov/Transmittals/downloads/R3100TN.pdf> on the CMS website. You may see the article related to the Q1 modifier, MM5805, at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5805.pdf> on the CMS website.

News Flash - It's Not Too Late to Get the Flu Shot. We are in the midst of flu season and a flu vaccine is still the best way to prevent infection and the complications associated with the flu. But re-vaccination is necessary each year because flu viruses change each year. Please encourage your Medicare patients who haven't already done so to get their annual flu shot. – And don't forget to immunize yourself and your staff. Protect yourself, your patients, and your family and friends. Get Your Flu Shot – Not the Flu! Remember - Influenza vaccination is a covered Part B benefit. Note that influenza vaccine is NOT a Part D covered drug. Health care professionals and their staff can learn more about Medicare's coverage of adult immunizations and related provider education resources, by reviewing Special Edition MLN Matters article SE0748 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0748.pdf> on the CMS website.

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