



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

Note: This article was revised on April 1, 2014, to add a link to SE1344 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1344.pdf>) that has information on an interim alternative method of satisfying the requirement in CR 8401 for providers who do not have the ability submit the clinical trial number for trial related claims. All other information remains the same.

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

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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

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.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html> 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.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> 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.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R3100TN.pdf> on the CMS website.

You may see the article related to the Q1 modifier, MM5805, at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM5805.pdf> on the CMS website.

You may want to review MM8401 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8401.pdf>) that alerts providers that, effective January 1, 2014, it will be mandatory to report 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", Section 310.1.

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