



Billing Routine Costs of Clinical Trials – JA6431

Note: MLN Matters® article MM6431 was revised to reflect a revised Change Request (CR) 6431 issued on June 26, 2009. The transmittal number, CR release date and the Web address for accessing CR6431 have changed. In addition, the implementation date was changed to September 28, 2009. All other information is the same.

Related CR Release Date: June 26, 2009 **Revised**

Date Job Aid Revised: July 8, 2009

Effective Date: July 10, 2009, For claims with dates of service on or after January 1, 2008

Implementation Date: September 28, 2009

Key Words MM6431, CR6431, R1761CP, Clinical, Trial

Contractors Affected

- Part A/B Medicare Administrative Contractors (A/B MACs)
- Medicare Carriers

Provider Types Affected

Physicians and non-physician practitioners submitting claims to Medicare Carriers and A/B MACs for clinical trials



CR6431 informs providers that they should continue to report the International Classification of Diseases diagnosis code V70.7 (Examination of participant in clinical trial) on clinical trial claims. **It is no longer necessary to make a distinction between a diagnostic and therapeutic clinical trial service on the claim.**

Provider Needs to Know...

- CR6431 revises Chapter 32, Section 69.6 (*Requirements for Billing Routine Costs of Clinical Trials*) of the Medicare *Claims Processing Manual*. CMS is clarifying that there no longer remains a need to make a distinction between a diagnostic versus therapeutic clinical trial service on the claim.
 - If the QV or Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, the Medicare contractor **will not** consider the service as having been furnished to a diagnostic trial volunteer.
 - Instead, they will process the service as a therapeutic clinical trial service.
 - Effective for claims processed 90 days after issuance of CR6431 with dates of service
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on or after January 1, 2008, claims submitted with either the modifier QV or the modifier Q1 will be returned as unprocessable if the diagnosis code V70.7 is not submitted on the claim.

- Providers will see the following messages from their Medicare contractor with the returned claim:
 - Claims Adjustment Reason Code 16 – "Claim/service lacks information which is needed for adjudication."; **and**
 - At least one Remark Code, which may be comprised of either:
 - The Remittance Advice Code (M76: "Missing/incomplete/invalid diagnosis or condition") **or**
 - The National Council for Prescription Drug Programs Reject Reason Code.

Note: Healthcare Common Procedure Coding System (HCPCS) codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., QV or Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

- On all outpatient clinical trial claims, providers need to do the following:
 - Identify all lines that contain a routine service with a HCPCS modifier of:
 - QV for dates of service before January 1, 2008, **or**
 - Q1 for dates of service on or after January 1, 2008;
 - Report condition code 30;
 - Report a secondary diagnosis code of V70.7; **and**
 - Identify all lines that contain an investigational item/service with a HCPCS modifier of:
 - QA/QR for dates of service before January 1, 2008; **or**
 - Q0 for dates of service on or after January 1, 2008.

Background	CMS is clarifying that there no longer remains a need to make a distinction between a diagnostic versus therapeutic clinical trial service on the claim.
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Operational Impact	N/A
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Reference
Materials

The related MLN Matters® article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6431.pdf> on the CMS website.

The official instruction (CR6431) issued regarding this change is available at <http://www.cms.hhs.gov/Transmittals/downloads/R1761CP.pdf> on the CMS website. The revised manual section is attached to the CR.
