Clinical Research Billing Compliance Frequently Asked Questions

Research billing requirements, codes, and modifiers

1. Do we need to report the National Clinical Trial (NCT) # for the study on claims?

Yes. Effective January 1, 2014, the Centers for Medicare and Medicaid Services (CMS) mandated the reporting of a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage (i.e. clinical trials, clinical studies, or CMS-approved Category A and B Device trials).

The number is assigned by the National Library of Medicine (NLM) http://clinicaltrials.gov website when a new study appears in the NLM Clinical Trials data base.

CMS uses this number to identify all items and services provided to beneficiaries during their participation in a clinical trial, clinical study, or registry.

For additional information, see CMS Medicare Learning Network Matters - MM8401.pdf

2. What special identifiers, codes and modifiers are required when billing for clinical study protocol items/services related to all Qualified Non-Device Clinical Trials?

Outpatient Clinical Trial Claims: On all outpatient clinical trial claims, institution / providers need to do the following:

- Report ICD-10 diagnosis code Z00.6 in the secondary position
- Report condition code 30 (Institutional Billing)
- NCT# (required for all as of January 1, 2014)
- Identify all lines that contain an investigational item/service with a HCPCS modifier of Q0 on or after 1/1/08
- Identify all lines that contain a routine service with a HCPCS modifier of Q1 on or after 1/1/08

Inpatient Clinical Trial Claims: Institutions / providers billing items/services that are routine costs of a Qualified Non-Device Clinical Trial must report:

- Report ICD-10 diagnosis code of Z00.6 in the secondary position
- Report condition code 30 (Institutional Billing only)
- NCT# regardless of whether all services are related to the clinical trial or not
- Q0/Q1 Modifiers are not reported on inpatient claims

For additional guidance, see Medicare Claims Processing Manual Chapter 32 (Rev. 3181, 01-30-15).

3. What does the Z00.6 diagnosis code tell the payor and when is it required?

The Z00.6 diagnosis code reports that the service involved "examination of participant in clinical trial". The Z00.6 diagnosis code must be used for all services provided as part of a Qualified Clinical Trial or approved study, even if it would otherwise be conventional care for the patient absent the trial.

4. Is it important where you place the Z00.6 diagnosis code?

The Z00.6 diagnosis code needs to be reported in the secondary position on the hospital and professional claim when billing for items/services related to a Qualified Clinical Trial or approved study regardless of whether all services on the claim are related to the clinical trial or not.

5. What does the Condition Code 30 tell the payor?

Condition Code 30 means "Qualified Clinical Trial". It must appear on the hospital inpatient or outpatient claim when billing for items/services related to a Qualified Clinical Trial or qualified study regardless of whether all services on the claim are related to the clinical trial or not.

6. What are the Q0/Q1 modifiers?

Q0-Investigational clinical service provided in a qualified clinical research trial

Q1-Routine clinical service provided in a qualified clinical research trial

7. **What is the purpose of the Q1 HCPCS modifier?**

   When billed in conjunction with the Z00.6 diagnosis code, the Q1 HCPCS modifier serves as the provider's attestation that the service meets the Medicare coverage criteria and is a routine cost of a qualified clinical trial. This is required under Medicare billing rules.

8. **If a patient is in a clinical trial, has finished active treatment and is being seen yearly for observation, do we will still need to include the National Clinical Trial (NCT) identification number?**

   No

Back to top