# UConn Health
## Office of Clinical & Translational Research
## Standard Operating Procedures

| Title: Billing of Routine Care Costs in a Qualified Clinical Trial | |
|---|---|
| Relates to Policy: 900-11, 901-11 | |
| SOP#: 1200-17 | Version 1.0 |
| Prepared by: P. Olsen | Original date: 10/03/2016 |
| Approved by: J. Kulko | Date approved: 10/03/2016 |

**Purpose and Applicability:** The purpose of this document is to describe the procedures that govern the identification and billing of routine care costs associated with a Medicare qualified clinical trial to ensure the compliant Medicare billing of these routine care costs at UConn Health.

**Background and Significance:** The Medicare National Coverage Decision of 2000 states that Medicare will cover the routine costs that are part of a qualified clinical trial. Section 310.1 of this NCD details the requirements for this coverage. As of January 1, 2014, it is mandatory to report a national clinical trial identifier (NCT #) on Medicare claims for items and services provided in clinical research studies under three policies:

1. the Clinical Trial Policy
2. the Investigational Device Exemption policy
3. Coverage with Evidence Development

In addition to the NCT #, Medicare also requires the inclusion of HCPCS modifier Q1 (routine service) or Q0 (investigational item or service) and a secondary diagnosis code of Z00.6 on these claims.[1]

No SOP exists at UConn Health that describes the overall process governing the insertion of the NCT number, appropriate modifiers and diagnosis code to the JDH and UMG patient bills for the routine costs in a qualified clinical trial.

**Scope:** Medicare coverage analysis (SOP 901-11) determines if a clinical trial is 'qualified' per Medicare guidelines and is done prospectively for all clinical trials opened at UConn Health. Patient charges associated with the clinical trial are identified as Protocol Induced or Routine Clinical Services. When a study has JDH and/or UMG charges associated with the study, a BEAN number is assigned to designate it as a clinical trial with JDH and/or UMG charges. Participants on most studies are assigned a STDY Case Number which allows all charges to be identified with the correct study. Based on the STDY Case, PIC charges are billed to Research.

When there are no PIC charges but there are RC costs associated with a qualified clinical trial, the participants are assigned a RSOC Case Number. The RSOC number designates routine clinical services and these charges are billed to Insurance. All charges incurred by patients with open case numbers are held for review.

The NCT# is required on Medicare claims only. The Q1 modifier and Z00.6 diagnosis code are currently being included on Medicare claims only, but may be required by commercial insurers as well. Medicare Advantage charges require special processing (SOP 1205-17)

[1] CMS website (CR 8041, MM5790, and MM8041).

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**Responsibilities:** When a Medicare qualified clinical trial opens at UCONN Health, the OCTR Fiscal Assistant:

1. Obtains a BEAN number to assign to the clinical trial
2. Obtains a STDY case number or an RSOC case number. The case number identifies the study to which any charges are to be billed

The Coding Reimbursement Specialist is responsible for reviewing UMG and JDH charges that are associated with an open case number and adding the NCT#, Q1 modifier, and Z00.6 diagnosis code if the charge is identified as requiring that information.

**Procedural Steps: See SOP 1201-17, 1202-17, 1204-17, 1205-17**

| Revision date: | Revised by: |
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