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 3.0
Prepared by: P. Olsen	Original date: 10/03/2016
Approved by: P. Hudobenko	Date approved: 6/22/18

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 patient is enrolled in a clinical trial that has charges in Epic (hospital and/or professional), and the patient has an 'Active' status in a clinical trial, **all** charges incurred by the patient are held for a two tier review in Epic to ensure the correct billing. The first tier review is usually done by the Study Coordinator who determines that the billing designation is correct (Research or Insurance). The second tier review is done by OCTR personnel. OCTR personnel can modify billing designation as well as charge information as necessary. When the first and second tier reviewers agree that the information is correct, processing through Epic continues.

The NCT# is required on Medicare claims only. The Q1 or Q0 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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The Coding Reimbursement Specialist is primarily responsible for second tier review.
The NCT#, Q1/Q0 modifier, and Z00.6 diagnosis code are automatically added in Epic.

Procedural Steps: See SOP 1205-17, 1207-18

Revision date: 6/22/2018; 7/12/17	Revised by: P. Olsen
3.0 Reason for revision: Modified charge review process due to the conversion to Epic 2.0 Reason for revision: Inclusion of Q0 modifier information	
Date revised version sent to archives & current revision version # advanced: 6/22/18	