UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Medicare Advantage Billing of Routine Care Costs in a Qualified Clinical Trial	
Relates to Policy: 900-11, 901-11	
SOP#: 1205-17	Version 3.0
Prepared by: P. Olsen	Original date: 10/04/2016
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 for clinical trial participants enrolled in a Medicare Advantage plan.

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. Also, 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. 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]

When a Medicare Advantage enrollee participates in a qualified clinical trial, the routine care costs associated with that trial are first billed to traditional Medicare. The patient is not responsible for Part A or Part B deductibles. The Medicare Advantage plan is responsible for the Medicare coinsurance amount minus the contractual copay, which is the patient's responsibility.[2] If the clinical services are covered by Medicare IDE or CED clinical trial policy, then the Medicare Advantage plan is the responsible payor.

Scope: When a Medicare Advantage plan is the primary insurer of a participant in a qualified clinical trial, per Medicare regulations, traditional Medicare becomes the primary insurer (for routine care costs associated with the trial) and the Medicare Advantage plan is responsible for the Medicare coinsurance minus the contracted copay. The clinical trial coding requirements for Medicare Advantage claims are the same as those for traditional Medicare claims. The charges for routine care that are part of a qualified clinical trial are billed to traditional Medicare with the NCT#, Q1 modifier, and Z00.6 diagnosis code. If services unrelated to the study are rendered the same day, the bill must be split with only the clinical trial routine care services going to traditional Medicare.

Responsibilities: The Coding Reimbursement Specialist is responsible for second tier review in Epic of charges associated with a patient who is active on a clinical trial. If the charge is identified as requiring the NCT#, Q1 or Q0 modifier, and Z00.6 diagnosis code, that information will be added via Epic backend processing. If the patient is enrolled in a

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[1] CMS website (CR 8041, MM5790, and MM8041). [2]Medicare Claims Processing Manual/Ch. 32/Sec. 69.9

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Medicare Advantage plan, Epic will change the primary insurance to Medicare if the charges are routine care costs associated with the clinical trial. For hospital charges, The required condition code for hospital charges will also be added via Epic processing. The balance remaining after receiving payment from Medicare will not be processed for secondary payment from the Medicare Advantage plan. If the charges are covered by Medicare's IDE or CED policy, then the Medicare Advantage plan is the payor and no change is necessary.

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3.0 Reason for revision: Conversion to Epic 2.0 Reason for revision: Inclusion of Q0 modifier information	
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