

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 1.0
Prepared by: P. Olsen	Original date: 10/04/2016
Approved by: J. Kulko	Date approved: 10/05/2016

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 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 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

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 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 services going to traditional Medicare.

Responsibilities: 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. If the patient is enrolled in a Medicare Advantage plan, the primary insurance is changed to Medicare. For JDH charges, the Coding Reimbursement Specialist is responsible. UMG personnel update the primary insurance for UMG

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

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charges. Billing Medicare Advantage for secondary payment is done by JDH and UMG personnel.

[K1]

Procedural Steps for Processing Medicare Advantage Claims in JDH and UMG:

For UMG charges:

A charge with a Q1 modifier and a Medicare Advantage insurance is held on a fatal edit. UMG personnel will process the claim to Medicare, and then send the balance to the Medicare Advantage plan.

For JDH charges:

From the Work Visit screen, enter 'IF' in the Action field.

If Medicare is already listed as an insurance, it must be moved to the first position.

Enter 'S' to swap plan order

Enter the appropriate numbers at the bottom fields to make Medicare (M850) first and Medicare Advantage second.

Hit F10 to get back to the Work Visit screen.

If Medicare has to be added as a Plan:

Enter 'A', 'A'

Enter Plan Code 'M850'

Hit F10

Make sure Medicare is the first plan listed and the Medicare Advantage plan is second. If not, then swap the plan order.

Hit 'F10' to get back to the Work Visit screen.

If M850 is not a valid plan, contact JDH Patient Services to add it. Once added, proceed as above.

It is recommended to follow up on the secondary processing of these charges.

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