UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Medicare Coverage Analysis Clinical Trials	
Relates to Policy/Procedures: 2006-06, SOP 900-11	
SOP#: 901-11	Version 4.0
Prepared by: Judi Kulko	Original date: 5/17/11
Approved by: Judi Kulko	Date approved: 8/28/17

Purpose and Applicability: To ensure that a Medicare Coverage Analysis is done by staff in OCTR for all research clinical trials that produce routine clinical services (RC) to be billed to Medicare and other insurers and protocol induced costs (PIC) to be paid by the sponsor.This procedure is done to adhere to the CMS National Coverage Determination of 2000 (NCD) and the process will include all clinical trials regardless of payer.

Background and Significance: Status of all new clinical trials relative to Medicare reimbursement for routine care costs must be determined before a study budget is negotiated, the study is submitted to the IRB, and the contract signed. The Medicare Coverage Analysis is a prospective certification of the "qualifying status" and delineation of protocol-induced costs (PIC) and routine clinical services (RC) done to assure that only those studies and charges that meet Medicare specifications for reimbursement will be designated as such. (See Appendix I & II attached to this SOP)

Scope: This SOP refers to all clinical trial projects involving research protocol induced medical interventions and routine clinical services generated from medical, behavioral, social science, outcomes and health services research involving human subjects conducted at UConn Health regardless of the payer. The following category of clinical trials/research is exempt from this policy and do not require a Medicare Coverage Analysis:

- •Retrospective (chart review) studies
- •Observational studies
- •Outcomes research
- •Tissue studies
- •Blood draw studies
- •Quality of Life studies
- •Nursing Research
- •Treatment Protocols, e.g. expanded access or compassionate use protocols

Responsibilities/ Procedural Steps: It is the responsibility of the OCTR Clinical & Administrative Research Coordinator, and the Reimbursement Coding Specialist under the supervision of the OCTR Executive Administrator, to:

- Gather all relevant documents
- Summarize the study information including aims of the trial phase of the trial, and indication of therapeutic intent
- Determine whether the trial qualifies for Medicare reimbursement

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- Draft a Coverage Analysis grid using the protocol schedule of events and the sponsor provided budget
    - Correspond directly with the PI regarding practice patterns for patients treated off protocol for same diagnosis
    - Use the information in the completed pre-packet budget workbook, prepared by the PI and research staff to identify services as being done solely for research versus those that are for routine clinical services (RC) including:
        - Medical management of patients with the diagnosis making he/she eligible for the clinical trial for patients treated on and off of a clinical trial
        - Provision of medically necessary services and frequency of such medical services for patients with same diagnosis and treated "off protocol" (conventional care)
        - Diagnosis or treatment of complications or prevention of complications
        - Administration of an investigational item or service
    - Use the Center for Medicare and Medicaid Services (CMS) to identify National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) to verify Medicare coverage for RCs associated with the trial
    - Use encoder program to verify Medicare coverage for RC's associated with the trial

- Assign any limitations on coverage (e.g., frequency of tests)
- Assign payers to each service
- To provide the completed analysis document to the PI and study coordinator for PI approval and signature and date
- Complete the process by signing and dating the analysis form

Responsibility of the PI:

- It is the responsibility of the PI to directly provide information in the pre-packet BWB to identify services that are RC or PIC based on medical necessity and frequency of medical services provided for patients treated "off of the study"

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- It is the responsibility of the PI to review the research final clinical calendar in the budget workbook and approve the delineation and frequency of medical services by signing attestation :
  - : *"In my role as the Principal Investigator of the following clinical trial…….. I verify that all costs identified as routine care in this budget workbook are medically necessary and are routinely performed on my patients and on the same schedule in the absence of a clinical trial".*
  - The form to be sign is the OCTR Verification Document that is also signed per OCTR SOP 900-11 to accept the clinical trial budget in the budget workbook.
- The clinical trial contract cannot fully executed until both statements and attending documentation is reviewed by the PI and signatures are affixed to both statements as a statement of approval

Current Assessment of Medicare Qualifications Form:

Study name:

_____

Principal Investigator:

_____

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Assessment of Medicare Qualifications for Payment for Clinical Trials (rev 8/5/10)

(Please **initial** appropriate response)

Dose the trial evaluate an item or service that falls within a Medicare benefit category & is not statutorily excluded from coverage? yes ___ no ___

Does the trial have THERAPEUTIC INTENT? (is not designed exclusively to test toxicity or disease pathophysiology) yes ___ no ___

Does the trial enroll patients with diagnosed disease rather than healthy volunteers? (Trials of diagnostic interventions may enroll healthy patients as control group) yes ___ no ___

IF "YES" TO ALL, THEN:

Is the trial:

Funded by NIH, CDC, AHRQ, CMS, DOD, VA? yes ___ no ___

Supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, VA? yes ___ no ___

Conducted under an IND reviewed by the FDA? yes ___ no ___

Exempt from having an IND under 21CFR 312.2? yes ___ no ___

Self-certified? yes ___ no ___

Qualify under Coverage with Evidence Development, CED? yes ___ no ___

IF "YES" TO ONE, THEN:

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TRIAL QUALIFIES UNDER MEDICARE NCD

Name of Reviewer: _____ Date of review: _____

MAY bill Medicare for:

Routine costs of a clinical trial when involved services and items are otherwise available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is no national non-coverage decision.

Routine Costs of a Clinical Trial include services or items**:**

1. Typically provided absent a clinical trial;

2. Required solely for the provision of the investigational item or service, clinically appropriate monitoring of the effects and/or complications; and

3. Needed for reasonable and necessary care arising from the provision of an investigational item or service, in particular for the diagnosis or treatment of complications.

MAY NOT bill Medicare for:

1. The investigational drug, device or procedure itself, (unless it is covered outside of research); or

2. Items and services provided SOLELY to satisfy data collection and analysis needs and not used in direct clinical management; or

3. Items and services customarily provided by the sponsor without charge; or

4. Items and services for which sponsor has specifically paid or provided; or

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5. Items and services for which there is no Medicare benefit category; or

6. Items and services that are non-covered because they are statutorily excluded or fall under a national non-coverage policy.

Revision date: 8/28/17 8/20/16; 8/20/13	Revised by: Judi Kulko
Reason for revision: 4.0 Reflect the addition of PI signature on attestation statement 3.0 Reflect changes to procedure regarding the specific documents needed for the analysis, exclusion of certain types of studies; statement that analysis will be done for all providers not only Medicare insured patients; name change 2.0 To reflect changes in procedure	
Date revised version sent to archives & current revision version # advanced: 8/28/17	