Medicare Coverage Analysis at The University of Southern California

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Medicare Coverage Analysis

- What?
- Why?
- When?
- How?

What is Medicare Coverage Analysis?

- Identifies the services for which Medicare will pay under the Medicare Clinical Trial Policy.
- Item of Billing Compliance
- The MCA lists all items and services to be provided as part of the clinical trial with notations of what should be billed to the research sponsor and what can be billed to Medicare.
- Notations are based on nationally recognized publications and other sources

Why is an MCA Required?

- Helps avoid compliance consequences with regard to inappropriate billing.
- To ensure appropriate reimbursement for the services provided to a patient in a clinical trial.
- Assists with Budget Build
- Generates ROF

Importance of Billing Compliance

- Penalties
- False Claims Act

Importance of Billing Compliance

- Rush University Medical Center- $1 million settlement in 2005 for improperly billing services as routine costs under the Medicare Clinical Trial Policy.

- USC Norris Cancer Center- $1.9 million dollar settlement, billed for services paid by sponsor and billed for services in non- qualifying trial.

- University of Alabama- $3.39 million settlement for falsely billing Medicare for procedures also billed to the sponsor

- Emory University- $1.5 million settlement for falsely billing Medicare and Medicaid for clinical trial services that were not permitted.

When Is an MCA Required?

- Medical Intervention to Patient
- Bill will be dropped for Services (ROF)
- Study Team Time and Effort

CTO and DCG

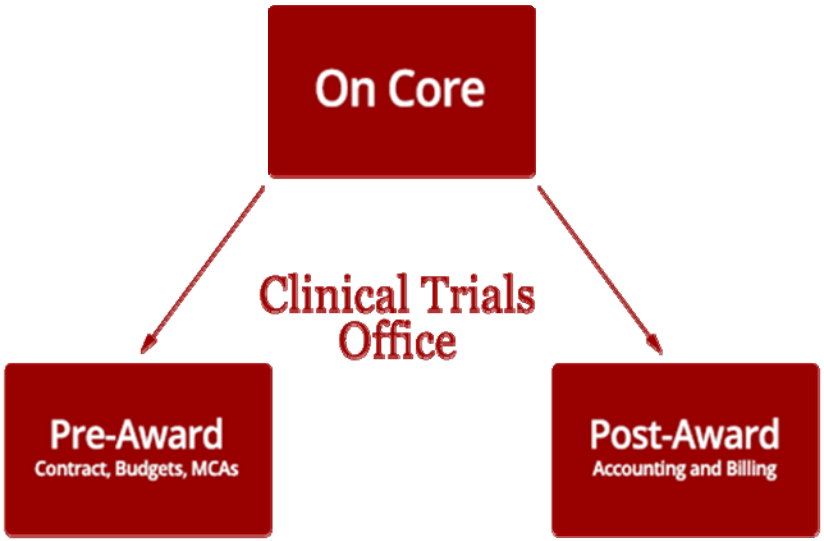
- Clinical Trial
  - DCG negotiates contract and budget for non-industry
  - CTO negotiates contract and budget for industry
  - CTO performs MCA review for all clinical trials regardless of funding source

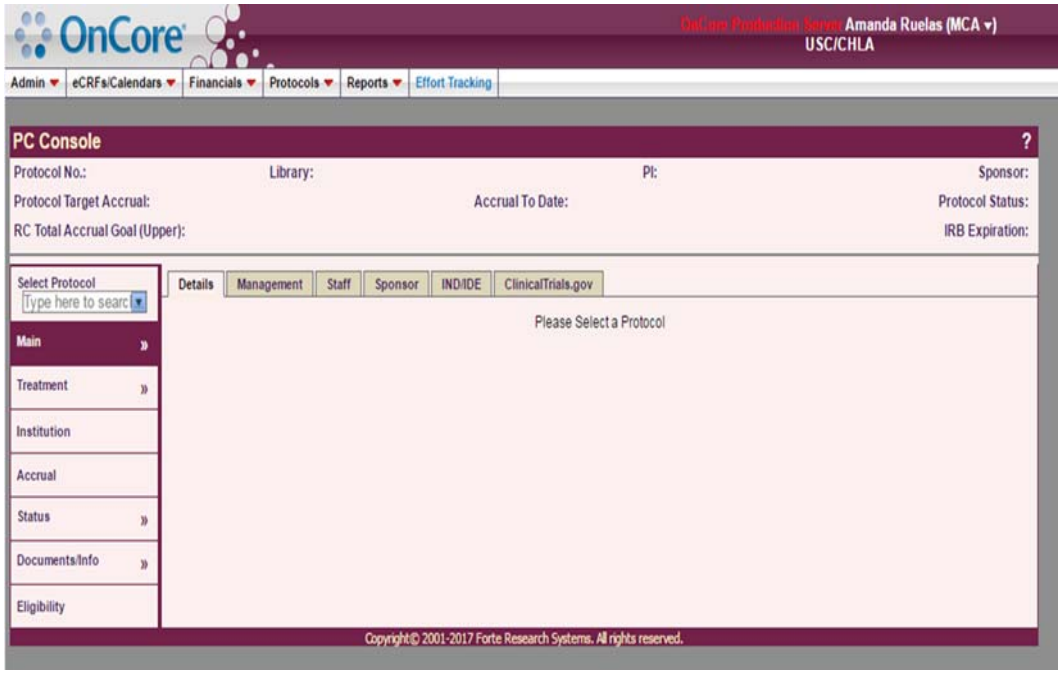
MCA Exemptions

- Studies where MCA exemption may apply:
  - Compassionate Use
  - Data Collection

- MCA exemptions are determined by CTO Coverage analyst during Initial Review

How are MCAs performed at USC





Items required to Begin & Finalize MCA

- Protocol
- ICF
- Budget
- Lab Manual
- Investigator Brochure
- Contract
- IDE/IND

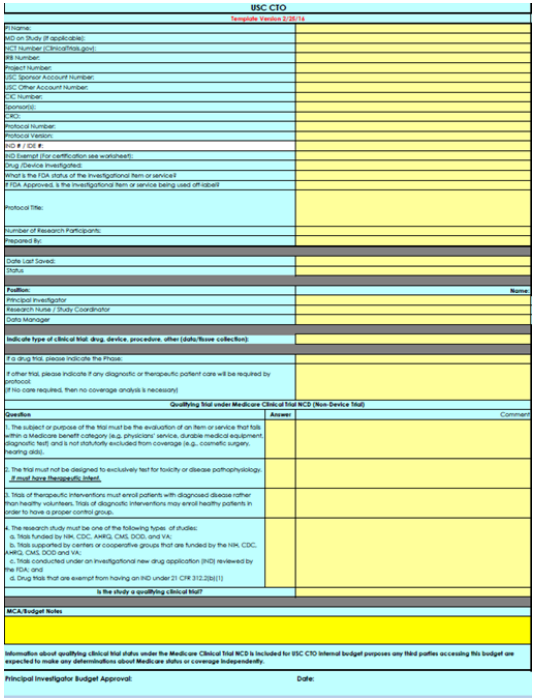
Determinations SOC vs Research

- National Coverage Determinations “NCDs”
- Local Coverage Determinations “LCDs”
- University Policies & Guidelines
- PI provides input to SOC vs. RES at kickoff meeting and signs MCA upon completion.

QCT Checklist

Requirements for Qualifying Clinical Trials

- A qualifying clinical trial (QCT) is a trial that meets the requirements set forth in Clinical Trial Policy (NCD 310.1) by the Center for Medicare and Medicaid Services (CMS).



USC CTO

Template Version 2/25/14

PI Name:	
MD on Study (If applicable):	
NCT Number (ClinicalTrials.gov):	
IRB Number:	
Project Number:	
USC Sponsor Account Number:	
USC Other Account Number:	
CIC Number:	
Sponsor(s):	
CRO:	
Protocol Number:	
Protocol Version:	
IND # / IDE #:	
IND Exempt (For certification see worksheet):	
Drug /Device Investigated:	
What is the FDA status of the investigational item or service?	
If FDA Approved, is the investigational item or service being used off-label?	
Protocol Title:	
Number of Research Participants:	
Prepared By:	
Date Last Saved:	
Status:	
Position:	**Name:**
Principal Investigator	
Research Nurse / Study Coordinator	
Data Manager	
Indicate type of clinical trial: drug, device, procedure, other (data/tissue collection):	
If a drug trial, please indicate the Phase:	
If other trial, please indicate if any diagnostic or therapeutic patient care will be required by protocol. (If no care required, then no coverage analysis is necessary)	

Qualifying Trial under Medicare Clinical Trial NCD (Non-Device Trial)

Question	Answer	Comment
1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g. physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).		
2. The trial must not be designed to exclusively test for toxicity or disease pathophysiology. *It must have therapeutic intent.*		
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.		
4. The research study must be one of the following types of studies: a. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA; b. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA; c. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and, d. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)		
Is the study a qualifying clinical trial?		

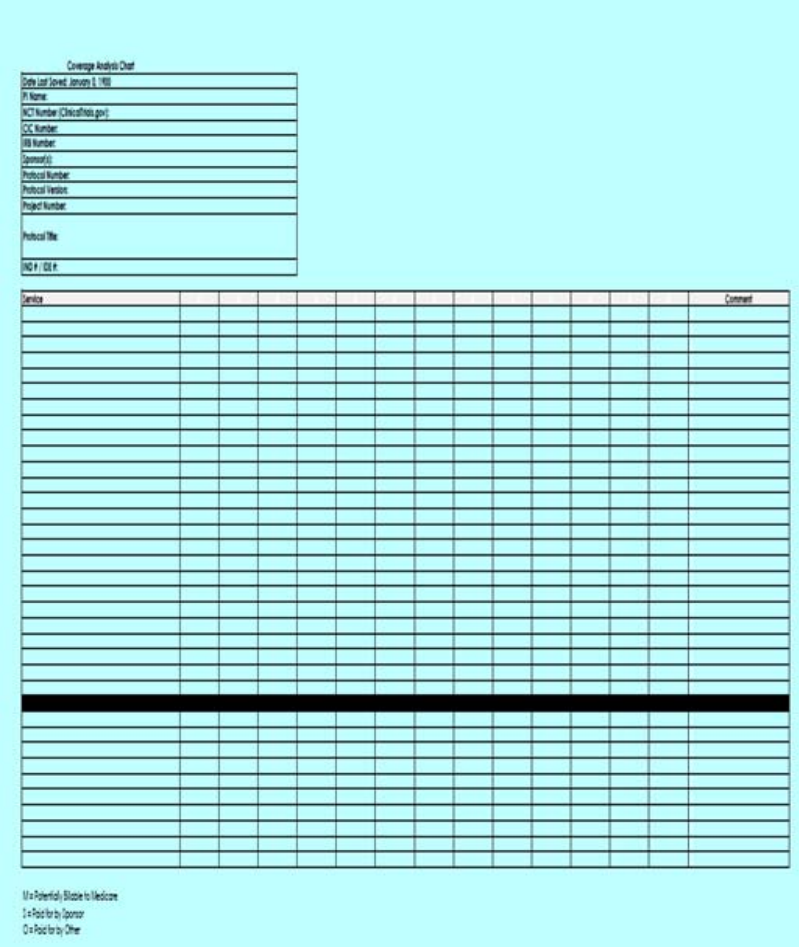
MCA/Budget Notes

Information about qualifying clinical trial status under the Medicare Clinical Trial NCD is included for USC CTO internal budget purposes any third parties accessing this budget are expected to make any determinations about Medicare status or coverage independently.

Principal Investigator Budget Approval: **Date:**

QCT Checklist	
1. Does the study require items or services that are potentially billable to a subject or third party payor?	
2. Which type of research is the study?	
3. If Non-Device, does the investigational item or service fall under a Medicare Benefit Category?	
a. If yes, what category?	
b. If Non-Device, does the study have therapeutic intent as an objective?	
i. If Yes, what is the objective?	
c. Does the study enroll patients with diagnosed disease?	
i. If Yes, what is the disease?	
d. Is the study a deemed trial?	
i. If yes, list IND # or does the study meet one of the other requirements for a deemed trial?	
4. If a Device study, does CMS allow coverage of the investigational device?	
a. Is the device FDA approved and used on-label?	
i. If no, does the device have an investigational device exemption (IDE) under 21 CFR 312.2(b) (1)?	
1. If Yes, what is the IDE number?	
2. If yes, what is the category for the IDE?	
a. If Category A, has the contractor determined the device is used for diagnosis, monitoring or treatment of an immediate life-threatening disease or condition?	
b. If Category B, has the contractor approved the use of the device?	
b. If device is investigational and does not have an investigational device exemption (IDE), does the device have a 510K exemption?	
i. If yes, what is the 510 exemption number? Obtain contractor approval before billing for services?	
5. If Observational, what is the general purpose of the trial?	
a. What did you use to determine the study is observational?	
b. What is the implication for Medicare Billing for the observational trial?	
6. Is this a Qualifying Clinical Trial based on Medicare guidelines?	
7. Comments:	

MCA and Calendar



Coverage Analysis Chart

Date Last Saved: January 0, 1900	
PI Name:	
NCT Number (ClinicalTrials.gov):	
CIC Number:	
IRB Number:	
Sponsor(s):	
Protocol Number:	
Protocol Version:	
Project Number:	
Protocol Title:	
IND # / IDE #:	

Service															Comment

M = Potentially Billable to Medicare
S = Paid for by Sponsor
O = Paid for by Other

V1 (New)

Clinical Procedure/Lab — Charge Master Version: 2 (12/15/2015)

	Procedure Expand All Collapse All	Billing Designation	Comments
	[+] Blood Draw	R	Performed for Research Purposes. Paid for by Sponsor
	[+] Shipping and Handling - research blood	R	Performed for Research Purposes. Paid for by Sponsor
	[+] Informed Consent	R	Study Staff Time and Effort
	[+] Data collection	R	Study Staff Time and Effort

Set Billing Designations

Foot Notes — Add

Index	Footnote	

Billing Designations	
S	Bill to Patient/Insurance
R	Bill to Sponsor
NA	Not Billable

Supporting Designations	
F	Forms
ICF	Promised free in Informed Consent
NA	Bundled Service, Not Separately Billable
NB	Not Billable
NR	Not Part of the Research Study

Study Calendar

- Nimblify
- Validation

Information to Expedite Your Study

- Study Submissions
- CTU Services
- Ancillary Committees
- Labs / Shipment of Specimen
- Pharmacy / Drug Accountability
- Etc.

CTO Contacts

- **Oncore Support –** OnCoreSupport@med.usc.edu
- **Oncore Submission –** Talena Sanchez Talena.Sanchez@med.usc.edu
- **Calendar** - Chris Ancheta Christopher.Ancheta@med.usc.edu
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