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

On Core
- Clinical Trials Office
  - Pre-Award: Contract, Budgets, MCAs
  - Post-Award: Accounting and Billing

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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).
MCA and Calendar
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
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