Phil B. Smith Neuroscience Institute

Tips & Challenges in Neurology Research Budgeting

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Holy Cross Health

Jim Moran Heart and Vascular Research Institute

Holy Cross Health

A Member of Trinity Health

Specialized Research Disease Areas and Populations – Cont.

The Phil Smith Neuroscience Institute brings together a multi-disciplinary team dedicated to improving patient care in the areas of ALS, neurology, neurosurgery, comprehensive stroke care, neuro-interventional radiology, epilepsy monitoring, sleep medicine, interventional spine, pain management, and more. The PSNI serves the community by providing cutting-edge treatments through various types of research.

A prime example of a trial which Holy Cross has conducted:

- Currently we are exploring efficiencies via interfaces in order to prevent this redundancy. The review of systems and their ability to interface is highly recommended when vetting new systems for institutional processes.
- Pre/Post Award offices: Clinical Research Operations office is charged with several of the Pre & Post award functions related to contracting, budgeting, invoicing, and budget reconciliation. Budget Analyst & Contract manager are notified via email that new studies have been uploaded into the contract management system.
- Getting data and documents submitted correctly on the front end i.e. during study start-up, helps dramatically with compliance and clean data in the downstream processes.
- Study team is also required to proof and sign-off on the study calendar in CTMS, upload IRB and ICF documents and add study staff by the date of the Study Budget orientation where the Research Account is released.

History of the NCD

- 1935
  - Social Security Act was enacted by the 74th congress & signed into law by President Roosevelt. The law created the SS program, creating social ins. Prog. Designed to pay retired workers age 65 or older.
- 1965
  - Congress passed legislation establishing the Medicare and Medicaid programs as Title XVIII and Title XIX, respectively, of the Social Security Act. (Lydon Johnson)
- July 7, 2000
  - President Clinton issued an executive memo directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs…and costs due to medical complications associated with participation in clinical trials."
- September 19, 2000
  - The Formal NCD was issued.

Foundation for Clinical Trials Offices

- Medicare Coverage Analysis (MCA) is not specifically required by name in the guidance but the implications of not having an MCA definitely impact compliance. The concept of the MCA was born out of the Rush settlement

NCD 310.1 Coverage of Routine Cost- Clinical Trials Policy

In order to support patient enrollment in clinical trials and the advancement of drug sciences, CMS implemented National Coverage Determination (NCD) 310.1 Clinical Trial Policy: "Coverage for Routine Costs in Clinical Trials" which states – "Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply."

The Medicare Program's July 9, 2007, version of the Clinical Trial Policy provided much of the framework for research billing compliance.

For Routine Costs in Clinical Trials(310.1)

In order for *Routine Costs* to be covered in a non-device trial, the study must meet the following three requirements:

1.The investigational item or service belongs to a Medicare Benefit Category

- These criteria are required for QCT

2. The trial includes therapeutic intent

- In order to become billable to insurance

3. The trial enrolls patients with a diagnosed disease.

NCD for Routine Costs in Clinical Trial- (310.1)
Determine if the trial meets *deemed* criteria for Medicare coverage of *Routine Costs*

- **Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;**
- **Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;**
- **Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and**
- **Drug trials that are exempt from having an IND under 21** CFR 312.2(b)(1)

NCD for Routine Costs in a clinical Trial (310.1)
Routine Costs include items and services that:

- Are ordinarily provided to Medicare beneficiaries outside of the trial;
- Are required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; or
- Are reasonable, necessary, and required to diagnose or treat complications associated with participation in the trial.

NCD for Routine Costs in a clinical Trial (310.1)
Routine Costs do not include items and services that:

- Are provided by the research sponsors free of charge for any enrollee;
- Are provided solely to satisfy data collection and analysis - not used in the direct clinical management of the patient; or
- Are investigational, unless otherwise covered outside of the trial.

Items which tend to specific to Neurology Trials Read the protocol thoroughly…

- Radiology Start-up Fees to Dept.- this is due to additional review and time for radiology staff.
- Phantom scans
- Calibration of MRI
- Tech time
- Radiology staff training for specific trials

Items which tend to specific to Neurology Trials

- Scales- multitude of assessment scales administered (time consuming).
- Complete Phy. Exam with Neuro Exam w/ MSE.
- Targeted Phy Exam w/ Neuro Exam includes MSE.
- Interim PI oversight fee (midway through study).

The End

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