Coverage Analysis

EFFECTIVE DATE: May, 2017

Purpose and Scope

This Policy describes the shared responsibility for performing the Coverage Analysis in development of a Clinical Trial budget. If a Clinical Trial requires patient care items and services (i.e., billable items/procedures/services such as those with Current Procedural Terminology (CPT), Healthcare Common Procedural Coding System (HCPCS), Diagnosis-Related Group (DRG) and International Classification of Diseases (ICD) codes) performed in furtherance of the Clinical Trial, then the Coverage Analysis Process shall be performed, as set out in this Policy, unless provided an exception by the University of South Alabama Office of Research.
This Policy shall apply to all Clinical Studies regardless of funding source (i.e. extramural industry funding, extramural non-profit or government funding, and/or intramural funding).

between research costs and routine costs to ensure proper billing of such costs to either the Clinical Trial Sponsor or a Third Party Payer.

Principal Investigator: (PI) Please see USA policy on Principal Investigators.

Qualifying Clinical Trial: is a Clinical Trial that meets the requirements outlined in CMS CTP, which may qualify for reimbursement of routine costs from a Third Party Payer.

Research Procedures: are the services and items required by the approved Institutional Review Board protocol and do not meet the definition of routine costs as defined by CMS.

Sponsor: is the organization that funds a Clinical Trial, often used interchangeably with funding agency. Third Party Payer/Payor is an organization other than the patient (first party) or health care provider (second party) involved in the financing of personal health services (e.g. Medicare, Medicaid, CHIPS, CSS, Aetna, Anthem Blue Cross, etc.).

Policy Statement

A Clinical Trial must have a budget that accurately and appropriately allocates the costs associated with performance of the Clinical Trial to the responsible payer (i.e. a Sponsor, Third Party Payer, or internal funding source). In order to ensure costs are allocated to the appropriate

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References

Center for Medicare & Medicaid Services (CMS) – National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) as subsequently modified by the Clinical Trial Policy (CTP) update of 2007.

Related Documents

Coverage Analysis Template

History

First Published May 2017

Next Review Date

May 2019

Responsible Party

Vice President Office of Research and Economic Development