Responsibility for Payment of Conventional or Routine Care in Clinical Trials

Subject: Responsibility for payment of conventional or routine care (e.g. items or services the participant would have received absent a research study) provided to study participants in research studies

UAB Position Statement: UAB cannot accept a sponsor's offer to pay for or provide items or services (including category B devices) identified as conventional or routine care "if insurance denies or if the service is not covered by insurance".

Acceptable Sponsor Language: The sponsor understands/expects that all items and services identified as conventional or routine care will be billed to the patient/patient's insurance. The sponsor will provide no payment for these items and services.

Basis: CMS (Center for Medicare and Medicaid Services) rules require that CMS study participants and non-CMS participants be treated consistently with respect to items/services paid for or provided at no cost by the clinical trial sponsor. For example, we can't provide a category B device at no charge for a Blue Cross patient and bill the device to insurance for a Medicare patient. The only exception to this position is for patients who are determined to be indigent based on UAB's charity care application process. For patient's meeting this exception, the sponsor would be allowed to pay for their conventional care items and services.

UAB Process:

- The UAB PI is responsible for review of the study protocol to determine those items that are "conventional care" items and services the patient would have absent the research study. The results of the PI review are (included in the bill-to-designation) are submitted to the Office of Clinical Billing Review for a Coverage Analysis and development of an Approved Billing Plan.
- The Office of Clinical Billing Review is responsible for (1) assessing the study against the Medicare Clinical Trial Policy to determine the appropriate study type for billing purposes, and (2) reviewing the conventional or routine care items included in the bill-to-designation against payer rules for UAB's existing payer mix to determine if there is a possibility of non-coverage by any payer.
    - There may be instances where protocol-required items/services could be identified as conventional or routine are based on the patient's clinical condition. In these cases, it is acceptable to bill those items/services to insurance for some participants, while those same items/services are billed to the study account for others whose clinical condition did not require the item/service. This would be identified during the coverage analysis process and documented in the approved billing plan.
- Any potential coverage issues by any of UAB's usual payers for conventional or routine care are communicated to the UAB PI and study team for inclusion in the budget negotiation process. When a potential coverage issue is identified for at least one of UAB's typical payers, one of the following options must be selected:
    - The sponsor will pay for the item or service for all participants; or

- The service will be billed to the patient/patient's insurance for all participants. It is important to make sure the informed consent document clearly specifies that some insurance companies may not cover all of the conventional or routine care and that the participant would be expected to pay for those items and services. In these instances, potential participants may choose not to enroll in the study for financial reasons.

- The result of the coverage analysis is an **Approved Billing Plan** that delineates all of the protocol-required items and services and specifying those which are billable to insurance (conventional or routine care) versus those performed for research only. During the course of the study, the UAB study team are required to follow this billing plan and submit CTBN's accordingly.

What if the sponsor refuses to remove the language from the contract? Sponsors must remove the language from the contract. UAB cannot participate in the trial if the sponsor will not remove the language.

Richard Marchase — 8/18/15 Date

Selwyn Vickers — 8/18/15 Date

Will Ferniany — 8/20/15 Date

Policy/Guidance References:

- Meade and Roach, Compliance Advisory: CMS Clarifies Medicare Coverage for Research Services, October 2008
- CMS Clinical Trial Policy https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html
- CMS MLN Matters SE0822 (1/9/09)