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

Selwyn Vickers
8/2/15

Will Ferniany
8/20/15

Policy/Guidance References:
- CMS Clinical Trial Policy
  https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html
- CMS MLN Matters SE0822 (1/9/09)
Responsibility for Copays/Deductibles for Routine Care in a Clinical Trial

Subject: Responsibility for copays and deductibles for conventional or routine clinical care (e.g. items or services the participant would have received absent a clinical trial) provided to study participants

UAB Position Statement: UAB cannot accept any language in a clinical trial agreement or award where the sponsor agrees to pay for or reimburse a study participant’s copay or deductibles for conventional or routine clinical care services provided in a research study. UAB expects the study participant will be billed for any and all copays or deductibles associated with any clinical items and services billed to their insurance.

Acceptable CTA Language: The study participant is responsible for all copays or deductibles associated with protocol-required items and services that are identified as conventional care, i.e. services the patient would have received absent the clinical trial.

Basis: CMS (Center for Medicare and Medicaid Services) views sponsor payments or reimbursements for conventional or routine care copays/deductibles as an inducement to study participants.

Allowable Exception:
- Exception: Sponsors of trials that meet certain federal requirements may be allowed to pay for or waive copays/deductible. If this language is included in any award or agreement, refer the document to the office of counsel for review. The Office of Counsel is responsible for conducting these reviews and will evaluate the project to determine if the federal requirements have been met.
- If sponsor payment or waiver of copays/deductibles is approved by the Office of Counsel, this information must be immediately communicated to the PI/Study Team, OIRB and the Office of Clinical Billing Review.
  - The PI/Study Team and OIRB are responsible for ensuring that the consent form includes appropriate language about the responsibility for copays/deductibles.
  - The Office of Clinical Billing Review is responsible for ensuring that the information is included in the clinical trial management system to sufficiently inform the Health System billing offices about how to bill copays/deductibles.

What if sponsor refuses to remove the language from the contract? Sponsors must remove the language from the contract unless the Office of Counsel approves the study with the language included.

Richard Marchase  
Date  
Selwyn Vickers  
Date  
Will Ferniany  
Date

Policy/Guidance References:
- CMS MLN SE0822, 1/9/09
- OIG Advisory Bulletin on Offering Gifts to Beneficiaries, 2002
- OIG Special Fraud Alert on Routine Waivers of Copayments and Deductibles, 1994)
Responsibility for Payment of Costs Associated with Subject Medical Injury in Industry-Sponsored Clinical Trials

Subject: Options for liability of costs for treatment of subject medical injury caused by participation in industry initiated and sponsored clinical trials or clinical studies

Defined Term: "Subject Injury Costs": As used in this document, the term "Subject Injury Costs" are the costs incurred by UAB for the immediate medical treatment for illness or injury that occurs as a direct result of the tests or treatments provided to a subject as a part of his/her participation in a clinical trial or study.

UAB Position Statement: UAB expects sponsors of industry-initiated and sponsored studies to select one of the options below with regard to responsibility for payment of costs associated with Subject Medical Injury.

- **Option A:** The sponsor will pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.
- **Option B:** The sponsor will pay for Subject Injury Costs for uninsured subjects or subjects with Medicare, Medicaid, Tri-Care or Champus (any federal payer) and to pay any part of Subject Injury Costs for privately insured subjects that are not covered and/or paid by their private insurance.

Basis: Center for Medicare and Medicaid Services (CMS) has documented that a Sponsor’s agreement to pay for costs to treat research related injury “if insurance denies” triggers the Medicare Secondary Payer rules in which case CMS states that the sponsor is responsible for payment for costs to treat injury, not Medicare.

UAB Process:
- If the Industry sponsor will not agree to pay for Subject Injury Costs in the clinical trial agreement, the Principal Investigator of the study is responsible for working with the Clinical Trials Office Administrative Director to develop an agreement with UAB Hospital stating that any Subject Injury Costs will be paid by the PI or his/her Department/Division/Center at the UAB Health System established research rates.
- This agreement will be documented in a Memorandum of Understanding signed by the Principal Investigator, the Chair of the applicable Department, the Dean of the School of Medicine and a representative of UAB Hospital.

Richard Marchase

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Policy/Guidance References:
- Compliance Advisory: Meade & Roach, LLP. CMS Issues Clinical Trials MSP Instruction, July 2010
- CMS’ 2004 Informal Position in the "Lutz Letter": CMS views clinical trial sponsor’s agreement to pay “if insurance denies” as a plan or policy of insurance under which payment can reasonably be expected to be made in the event such injury occurs.
- 42 C.F.R. Section 411.50: Medicare is secondary to any liability insurance plan that is required or responsible to pay based on “legal liability for injury or illness or property damage.”