

01/15/2025

RE: Institutional Policy Regarding Billing Coverage Analysis of Clinical Human Subject Research.

To ensure compliant clinical research billing, The University of Texas Health Science Center at Houston (UTHealth), requires a billing coverage analysis (CA) to be completed for all clinical studies submitted to the Internal Review Board (IRB).

A billing coverage analysis (CA) is an independent review of a human research study to determine which clinical procedures and services are billable to insurance and which are not. In addition, if the study meets the criteria of a “Qualified Trial” we must include the National Clinical Trial Identification number (NCT) along with research codes and modifiers on our routine care claims associated with participation in the study. This process involves a systematic review of clinical trial documents, published practice guidelines, local coverage determinations (LCD), and national coverage determinations (NCD) to determine the billing status of items and services that are documented in the research protocol and/or research plan.

The fees for CA at The University of Texas Health Science Center Houston (UTHealth) are non-negotiable and are applied to all Industry sponsored clinical studies as follows:

Study Complexity Level	Initial CA Fee	General Characteristics	CA Amendment Fee
Low	\$2,069	Simple studies with few services/procedures. Items tend to be paid for by the sponsor- example would be simple sample collection study.	\$830
Medium	\$3,448	Most clinical trials fall into this category. Items will be both sponsor paid and conventional care. Studies will several study- specific services and procedures outlined by the protocol, but will be limited to one arm.	\$1,105
Complex	\$4,285	These studies have a high number of conventional care services and procedures. These studies may involve multiple cancers and/or multiple arms.	\$1,660
Exceptionally High	\$4,820	Exceptionally High complexity studies are usually federal awards. These studies must have multiple arms, and they typically involve multiple cancer sites. Most of the procedures in these studies are conventional care, and the volume of procedures greatly increases the coverage analysis development time. Examples of these studies include COG, MATCH, and immunotherapy.	\$2,678

UTHealth has collected pricing data from peer institutions regarding these standardized fees and confirmed our fees are competitive with other institutions and provide value for our industry partners.

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