

Question 1: What is a coverage analysis and where/what are the CA fees?

Coverage Analysis defined:

Coverage analysis is the process of reviewing a clinical trial protocol and determining which items and services can be billed to the study sponsor, and which can be billed to insurance. The process is crucial to the administrative wellbeing of a study and can prevent costly errors that lead to billing non-compliance.

When the analysis is complete, the investigator receives a study-specific billing summary that lists all items and services (exclusively those items/services that are ordered via Epic and performed at UT Southwestern Medical Center or a UTSW-affiliated facility) to be provided as part of the clinical trial with notations of what should be billed to the research sponsor and what can be billed to insurance, based on Medicare rules. These billing grids are a valuable tool to ensure appropriate billing.

Coverage Analysis fees:

All clinical services, items or procedures billed to study sponsors, study subjects, and/or study subjects' Medicare, Medicaid, or other third-party payer(s) must be:

- a) consistent with applicable federal and state billing rules of the third-party payer being billed;
- b) consistent with any grant provisions or contractual obligations entered into by UT Southwestern Medical Center;
- c) consistent across all study related documents, including the protocol, grant/contract, budget, and informed consent document; and
- d) consistent with practice plan procedures that establish standards for professional billing.

UT Southwestern Medical Center (UTSW) charges an Institutional CA review fee of \$500 for initial review of all industry-sponsored and industry-developed clinical research studies. For clinical research studies deemed as qualified clinical trials and/ or those that include billable items and services, an additional \$3,500 fee is assessed. SPA will assess a fee of \$1,500 for CA amendments/modifications. This fee will be assessed for each CA amendment/modification request submitted in Velos, which generates at the request of an industry or corporate sponsor.

Billing and payment are handled as follows: The Office of Clinical Research Services, Sponsored Programs Administration, will invoice the sponsor upon contract execution and at the time of initial invoicing for the study. Study accounts will be assessed these fees at the initial award set-up. All payments received by the sponsor will be deposited to the University clearing account and credited to the study account.

Resources

[Medicare Coverage Analysis Review Fee Letter](#)

[Sponsored Programs Administration website](#)