

Research Billing and Coding

Health related services or procedures within a health system department that are provided as part of a clinical trial must be billed accurately. Accurate billing for research-related services is dependent on study documentation specificity.

The research protocol and other study related documents must clearly and comprehensively summarize researchrelated procedures and services. All procedures and services within a research protocol should have an associated CPT, HCPCS, or other available billing code.

Study documents may include, but are not limited to:

- Informed Consent Form (ICF)
- Clinical Trial Agreement (CTA)
- Sponsor Agreement
- · Qualified Clinical Trials (QCT) form
- · Billing Grid
- Billing Calendar
- Research Coding and Pricing

Study teams can obtain research coding and pricing information either by the self service Charge Description Master or submitting the research coding and pricing request form to Centralized Research Business Partners (CRBP).

The Charge Description Master provides a comprehensive list of CPT and HCPCS codes with corresponding Industry and Non-Industry research prices. Pls and study teams can use this information to perform a preliminary feasibility analysis.

CRBP can assist with complex studies and will provide a detailed analysis and estimate of research costs, via the Research Coding and Pricing Request form. CRBP in collaboration with Financial Coverage and Activation (FCA) will develop a billing calendar in Oncore that will identify all pertinent CPT and HCPCS codes and associated research prices.

Research Billing

Research-related health-care services must be billed consistently to the appropriate payers for each enrolled subject, in accordance with the study-specific documentation. Inconsistent billing for research-related services results in billing compliance issues.

All billable research related services should have charges dropped into the electronic Health record through established charge submission workflows. Research subjects should be encountered at the department/clinic that they are receiving services and that visit encounter linked to the clinical trial that they are receiving services for.

Charges filed during the research related encounter will flow through the revenue cycle and be directed to the appropriate payer based on the study specific billing calendar or default settings that send the charges for review by the CRBP team. The CRBP team reviews charges that are generated within research-linked encounters. They use available study documentation to direct charges as follows:

• Research-Related - Bill to Sponsor



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- The service is identified in the study documentation as billable to sponsor.
- Research-Related Bill to Patient
 - The service is identified in the study documentation as not billable to sponsor. A charge generated for a study with Medicare Qualified Study status requires research-related codes and modifiers.
- Not Research-Related Bill to Patient
 - The service is not identified in the study documentation and is not related to the study.

Once charges have been adjudicated by CRBP, undetermined charges or research related charges are sent to study team for review on the transaction report. A charge directed to the patient account will be processed according to the usual revenue cycle workflow, involving charge flow to government payers, insurance companies, and other pertinent payers.

Transaction Report

Every week CRBP will send study teams a Hospital Billing (HB) and/or a Professional Billing (PB) Research Transaction Report. Both reports are directed to designated study contacts for review and validation of each pertinent charge.

Study teams are responsible for notifying CRBP if charges should be directed to the patient's guarantor account rather than the study account. Study teams are responsible for notifying CRBP of any legacy pricing by manually adding the budgeted cost to the transaction report and returning the completed report within the designated time frames. All charges on the transaction report will be directed to the appropriate study FAU account with or without study team response.

Additional Resources:

- Related Billing Guidance and References
- Noridian Clinical Trials Coverage and Billing Guide
- Clinical Trial Contract Checklist

Contact the CRBP team at <u>UCLAHSCRBP@mednet.ucla.edu</u> if you have questions.

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