Appendix A: Clinical Research Billing Responsibilities and Process

RESPONSIBILITIES BY OFFICE

Clinical Billing Review (CBR):

  Responsibilities include:
- Performing and maintaining coverage analysis for each clinical study
- Finalizing and approving a billing plan delineating those services which should be billed to the research study versus the participant or third party payer as standard care; and
- Communicating the results of the coverage analysis and approved billing plan to the Division/Department designee, UAB Centralized Business Office, OSP, and OIRB, as appropriate.

OnCore Enterprise Team (OET):

  OET is responsible for the overall operation (coordination, education, and oversight) of OnCore, the University-wide clinical trials management system (CTMS). The OnCore Clinical Trial Management System (Advarra Inc.) is used for operations/data management, budget/billing, scheduling, and tracking of clinical research.

UAB Medicine Business Support (UMBS) / Clinical Billing Offices (CBO):

  Responsibilities include:
- Creating, Updating, and Providing the uniform clinical trial research fee schedule
- Providing coding and pricing information for CBR, OET, and PowerTrials for budget management and study set-up for OnCore Calendar and PowerPlan
- Receiving and processing participant visit information via SMR electronic CTBNs
- Coding and generating claims in accordance with applicable billing regulations and contractual obligations

Institutional Review Board (IRB):

  The IRB is responsible for ensuring that the results of CBR's preliminary review of the informed consent documents are incorporated into the IRB review process.

Office of Sponsored Programs (OSP):

  OSP is responsible for ensuring that any language in the study's contract relevant to billing practices is congruent with the institution's position.

Principal Investigator and Research Staff
Principal Investigator (or department designee)

  The PI is responsible for the following specific steps:

1. Providing to the Office of Clinical Billing Review (CBR) the study protocol (including amendments requiring addition or deletion of clinical items/services), proposed clinical trial agreement (CTA) (for device trials only), proposed informed consent document (IC) (including amendments related to adding or deleting clinical items/services), and a billing plan (i.e. clinical interventions/interactions and research activities designated by the protocol) with each event assigned to a standard treatment or research category to obtain a prospective coverage analysis of billable clinical services

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2. Reviewing and accepting the approved billing plan and/or OnCore Calendar generated by CBR for the project
3. Negotiating the study budget with the sponsor. In the event the PI is agreeing to supplement the cost of the study, such cost sharing commitment must be approved prior to contract execution as described in the UAB Cost Sharing Policy
4. Communicating study and participant visit information to the appropriate UAB/UAB Medicine units
5. Verifying claims from the Clinical Billing Offices (CBO) for accuracy and processing payments
6. Providing timely submissions to UAB's research administration offices, including the Office of the Institutional Review Board (OIRB) Office of Sponsored Programs (OSP), and Conflict of Interest Review Board (CIRB), as well as amendments and changes required by each of the research administration offices
7. Providing OSP a copy of the final budget before execution of the Clinical Trial Agreement

Initiation of OnCore clinical trials management system (O'Neal Comprehensive Cancer Center)

- Establishes study in OnCore using basic prescribed study information
- Forwards new and amended study/research submissions (referenced above) to CBR for billing compliance review of clinical billable items/services
- Ensures that itemized research activities are not designated as clinical billable items/services in OnCore

Prospective Billing Coverage Analysis

- Electronic copies of documents automatically sent to CBR if indicated in OnCore submission that UAB Health System clinical billable services are included in study. Documents sent include proposed CTA (if device trial), proposed Informed Consent document, research protocol, Billing Plan (i.e. clinical interventions/ interactions and research activities designated by the protocol) with each event at each study visit assigned to a standard treatment or research category.
- Reviews billing plan from CBR and initiates it
- Sends the following modifications to the research study to CBR for review:
  - Protocol amendments requiring addition or deletion of clinical procedures or ancillary services (e.g. radiology, lab, cardiographics, etc.)
  - Changes in sponsor funding for study clinical procedures or ancillary services (e.g. radiology, lab, cardiographics, etc.)
  - Change in billing designation (research versus standard treatment)
  - Change in location of the study activity
  - Change in PI for the study
  - Change in study personnel

(Electronic Method)

- Creates patient record and associates it with study in OnCore
- Schedules participant appointments in OnCore
- Verifies completed appointment in OnCore which electronically transmits Clinical Trial Billing Notice (CTBN) to billing entities

Study Financial Management

- Enters budget per executed contract
- OnCore generates invoiceable items as study team enters activity into OnCore (participant visits, financial events, additional procedures, etc.)

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- May create electronic invoices that may be exported out of OnCore and sent to sponsors for payment (optional)
- May post receipt of payments from sponsor in OnCore (optional)
- May allocate payment from sponsor to invoices in OnCore for reconciliation (optional)
- May generate financial reports in OnCore (optional)

Processing Study Payments

- Receives and processes internal invoices from billing entities for payment by Sponsor using the following steps:
  - Comparing the invoice with the study budget for correctness
  - Working with billing entities to correct inaccurate invoices, as necessary
  - Processing payments to billing entities

OnCore Calendar Services (OCS)

- Receives submission of study information from PI/study team
- Reviews submissions and directs CCC submissions to CBR as applicable
- Creates OnCore protocol shell and Calendar for new Medical Enterprise studies, updates OnCore calendar for revisions to Medical Enterprise studies
- Adds Protocol-Related Items to the Financials Console per the "**UAB Financial Recommendations for Industry-Sponsored and Funded Clinical Trials**"
- Exports OnCore calendar and reformats into template billing plan for studies requesting new or revisions to existing UAB Health System clinical billable services and/or CCTS services and sends to study team for completion
- Upon receipt of completed billing plan from study team, updates OnCore Calendar and sends Billing Plan to CBR and CCTS, if applicable
- Upon completion of required reviews and any updates from CBR and CCTS, if applicable, sends OnCore Calendar to Study Team for validation, makes any additional changes, and marks calendar 'Complete' once study team validates
- Send changes requested during validation that affect UAB Health System clinical billable procedures or CCTS services to CBR and CCTS, if applicable

Clinical Trials Administrative Office

Office of Clinical Billing Review (CBR):

Prospective Coverage Analysis

- Enters receipt of study in electronic tracking database and assigns Fiscal Approval Process (FAP) number
- Performs preliminary review of the protocol, billing plan and informed consent form (ICF) to determine whether:
  - Study qualifies for coverage under applicable CMS Clinical Trial Policy (CTP)
  - Any protocol designated items/services will be billed to participants or third party payers as routine costs as defined by the CTP
    - Routine costs exclude the following:
      - Investigational item or service unless the item or service is otherwise covered outside of the clinical trial

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- - Items and services provided solely to satisfy data collection and analysis needs and is not used in the direct clinical management of the patient
  - Items and services provided by the research sponsor free of charge for any enrollee in the trial
  - o Protocol, billing plan and ICF are consistent regarding:
    - items the sponsor is providing at no cost to all study participants
    - items/services to be billed to participants or third party payers as routine costs
    - costs related to items and services needed for reasonable and necessary care arising from the provision of the investigational item or service - in particular, for the diagnosis and treatment of complications

- Communicates results of preliminary review to department designee, IRB and OSP
- Ensures compliant billing plan by:
  - o Performing detailed prospective coverage analysis on each protocol designated item and service based on investigator-assigned category of routine cost or research
  - o Documents the rationale for compliant billing to insurance for each SOC study activity and its frequency
  - o Obtaining research pricing and coding for UAB Health System clinical billable services
  - o Assigning appropriate CPT/charge codes for all clinical billable activities in the OnCore system by linking items from the OnCore Chargemaster to the OnCore Calendar
- Exporting and sending approved OnCore Calendar to study team for review and approval

UAB Health System Information Services (HSIS)

PowerTrials Team

- After research coordinator confirmation of protocol-required services in the Oncore calendar, the PowerTrials team begins the PowerPlan process
- The PowerTrials team requests the necessary information for the PowerPlan build from Radiology Research, Investigational Drug Services, and lab coordinators. Once received, the PowerTrials team builds the PowerPlan
- PowerPlan builder sends completed PowerPlan to PI/Coordinator for validation
- Following validation by PI/Coordinator, testing is scheduled
- Once it passes testing, the plan is built in Production and a final validation is requested
- The PowerPlan is then released for active use

UAB Medicine Finance

On an annual basis, updates and communicates the uniform clinical trials research fee schedule.

Centralized Business Office – UAB Medicine

UAHSF Management Services Organization (MSO)

- Creates study account in billing system, IDX, from SMR or manually from CTBN study notification
- Establishes a patient "case" in IDX either from SMR data feed or from the electronic or manual CTBN
- Receives scheduled participant appointments electronically or via electronic or manual CTBN
- Matches scheduled participant visits in SMR to scheduled visits in IDX
- Receives occurred visit information electronically via electronic or manual CTBN

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- Processes charges as directed on the CTBN
- Generates claims to appropriate payers
- Receives and post study payments accordingly

Hospital Lab

- Creates a lab billing account in HealthQuestion (HQ) via CBO notification/price request or SMR data feed
- Verifies lab charges on lab billing slip or electronic CTBN are accurately assigned to the correct account

Patient Financial Services (PFS)

- Receives electronic or manual CTBN
- Identifies clinical trial accounts in billing system, HealthQuest (HQ), using SMR electronic CTBN feed or manual CTBN generation
- Reviews specific items/services provided via electronic or manual CTBN
- Reviews patient account in HQ with corresponding CTBN
- Generates claims to appropriate payers
- Receives and posts study payments accordingly