**What is Coverage Analysis?**

Coverage Analysis is the review of the proposed UAB Health System Billable Items/Services to ensure appropriate billing to insurance or the study, per the CMS NCD 310.1 (Routine Costs in Qualifying Clinical Trials) which states,

“*Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.*”

Coverage Analysis Includes:

* Determining and documenting whether or not the trial is Qualifying per Medicare rules (Study Type)
* Documenting routine care for UAB Health System items/services planned to be billed to insurance and confirm that the item/services meets indications and limitations for Medicare coverage
* Confirmation of CMS Approval for Category A, Category B Device trials and CED trials
* Review of the informed consent document to ensure there is no problematic language (the study team/sponsor may not pick up the cost of an item/service if insurance does not cover/denies; if promised free in the consent, insurance may not be charged for item/service; costs to the participant need to be clearly communicated in the consent form, etc.)
* Communication to the study team, the Institutional Review Board (IRB) and the Office of Sponsored Programs (OSP) any billing limitations and/or problematic language (the study team/sponsor may not pick up the cost of an item/service if insurance does not cover/denies; if promised free in the consent, insurance may not be charged for item/service; costs to the participant need to be clearly communicated in the consent form, etc.)
* Facilitate coding and pricing for UAB Health System Clinical Billable Services between the Clinical Billing Offices (CBO), Revenue Integrity, and the Study Team

**What is a UAB Health System (UABHS) Clinical Billable?**

Any clinical service performed during the conduct of a research study (on the protocol schedule of events or listed as a procedure on your IRB Human Subjects Protocol) that is billed through the UAB Clinical Billing Offices (MSO/HSF and/or PFS).

***NOTE***: *UAB Health System Billables may be billed to the research study and/or to insurance. If any UABHS Clinical Billable Services are billed to insurance, the trial must be reviewed by CBR.*

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| **Examples of UABHS Clinical Billable Services:** |
| **Procedure** | **Performed By** | **Billed By** |
| X-Rays, MRIs, CT Scans or other Radiological Procedures  |  TKC Staff, Hospital staff, Whittaker Staff, Highlands Staff, etc – UAB Radiology | UAB Health System Billing Offices |
| ECG | TKC Staff, Hospital Staff, Whitaker Staff, etc | UAB Health System Billing Offices |
| Echo | TKC Staff, Hospital Staff, Whitaker Staff, etc – UAB Echocardiographics | UAB Health System Billing Offices |
| Pulmonary Function Tests | TKC Staff, Hospital Staff, Whitaker Staff, etc | UAB Health System Billing Offices |
| Local Labs | UAB Hospital Labs (\****NOTE: If local labs are performed in CRU, they may be resulted by UAB Hospital Labs – check with CRU or CBR if questions***) | UAB Health System Billing Offices |
| Shipping and Processing to a Central Lab | UAB Hospital Labs  | UAB Health System Billing Offices |

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| **Examples of Non-UABHS Clinical Billable Services:** |
| **Procedure** | **Performed By** | **Billed**  |
| Clinical Procedures Performed in a Research Lab or Research Unit that does not bill through the UAB Health System | Research Staff (Research Nurse, PI, etc) | N/A – not billable through the UAB Health System |
| X-Rays, MRIs, CT Scans or other Radiological Procedures performed outside the standard for this scan (scan itself or just the data transfer fees, etc)***(\*NOTE: Questions - Rad Research******radresearch@uabmc.edu***) | Research Radiology | By Research Radiology directly to the Study Team |
| ECG | Study Team | N/A |
| Central Labs | Study Team(\****NOTE: If local labs are performed in CRU, they may be resulted by UAB Hospital Labs – check with CRU or CBR if questions***) | N/A |
| Shipping and Processing to a Central Lab | Study Team | N/A |

**What is a Research Practice Expense (RPE)?**

A fee to the research study for a date of service where protocol-related activities are taking place in a location billed by HSF/MSO where no revenue for HSF/MSO is generated at this visit – no HSF/MSO billables are billed through the UAB Health System for the visit.

Example: You are performing non-HSF/MSO UAB Health System research activities (i.e. informed consent, questionnaires, etc.) in an HSF/MSO clinical space (TKC, Whittaker, WIC).

***NOTE:*** Hospital Lab is billed by PFS UAB Health System Billing Office, so if you are performing these non-billables in one of these locations, but you are having labs performed by one of the labs (TKC, Whitaker, WIC), an RPE will still apply b/c there are still no HSF/MSO billables for the date of service.

**Radiology Research**

If your trial includes radiology procedures, you will need to also submit the study directly to Radiology Research. You may receive bills from both Radiology Research and the UAB Health System Billing Offices.

Please see the link below for the application. Please contact Radiology Research directly for any questions or concerns. Contact information: (205) 975-4559 / radresearch@uabmc.edu

**Link for Rad Research RedCap Application:** <https://redcap.dom.uab.edu/surveys/?s=PJPANNA439>

***Additional Notes Regarding Submission:***

*\*\*The Tumor Metrics request is ONLY for exams not ordered in IMPACT for Metrics, we are NOT requiring this to be entered for all metrics studies*

*\*\*The oracle account number is a required field on multiple documents, for CCC studies please enter 999999*