PURPOSE

Establish the coverage analysis requirements and processes for handling clinical services associated with clinical research studies. The coverage analysis includes the determination of the responsible party for the costs of such clinical services in a clinical trial where a billing risk *(per SOP-004_ResearchBillingRisk)* is present. This applies to all clinical trials that have the following:

- Clinical (or patient) services or items used to provide conventional patient care or research procedures required by the study plan
- Services or items required by the study plan that are entered into a clinical patient billing system (e.g., EPIC, Meditech, Sunrise/IDX, etc)

BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) coverage rules for clinical research services are stated in the National Coverage Determination Policy (NCD 310.1), most recently revised in July 2007. According to this policy, Medicare will reimburse for additional costs incurred by the participants in qualifying clinical trials. These additional (expanded) costs may include administration of the investigational item (e.g., chemotherapy infusion), clinically appropriate monitoring (e.g., additional labs to monitor for side effects of the investigational medication), diagnosis, prevention, and treatment of complications. In order to receive the reimbursement for expanded services, the study has to "qualify." The NCD specifies the qualification process for clinical trials, including covered indications, limitations of coverage, and other requirements. Medicare coverage for clinical trials is limited to items and services that are reasonable, necessary, and within the scope of a Medicare benefit category. If services are only being conducted for data collection and not reasonable and necessary, the service is non-covered, and therefore, should be paid for by the study budget.

Please Note: *The Clinical Trial Policy National Coverage Decision (NCD) was issued by the Center for Medicare and Medicaid services (CMS). Non-governmental payers (i.e. Blue Cross, Aetna, etc.) may have their own coverage of services policies related to clinical trials. For non-governmental payers, it is the responsibility of the research site or the research participant to determine if a service provided within a trial is covered.*

RESPONSIBILITY

Clinical Trials Office Staff - Designated CTO staff are responsible for performing the coverage analysis by reviewing human subject research studies that have a patient billing risk to ascertain the appropriate payer for services provided as part of the clinical research study. The following responsibilities also apply:

- CTRC CTO – provide coverage analysis support for all cancer-related studies. Submit the coverage analysis results to VPR CTO.
- VPR CTO – provide coverage analysis support for all studies that are not cancer-related. Submit coverage analysis results for cancer and non-cancer studies to the Office of Clinical Research as part of the Institutional Review.

Research Team (RT) – Provide relevant documents and study information as requested by CTO staff. Communicate patient activity, services provided, and billing instructions to the appropriate billing entities.

Principal Investigator (PI) – Review completed coverage analysis for accuracy and to confirm agreement.

RELEVANT DOCUMENTS, as applicable

- Completed Billing Risk Questionnaire form (BRQ). *This form is available for completion in Velos eResearch for those studies entered into the system. Refer to *Velos Work Instruction – Research Billing Risk* for instructions on completing the form in eResearch.
- Research Protocol*
- Informed Consent Form*
- Clinical Trial Agreement (CTA), Notice of Grant Award (NOGA) or other Funding Agreement*
- Budget*
- Documentation of the drug or device status with the FDA [e.g. Investigational New Drug (IND) number, Investigational Device Exemption (IDE) number, 510k approval], if available
- Research Activity Billing Trigger (RABT) MS Excel workbook, as needed – the RABT serves to document the billing grid and coverage analysis, as well as to communicate the billing instructions to the appropriate billing entities for each participant and services provided per each participant. *Refer to *Velos Work Instruction – Coverage Analysis* for instructions on completing the billing grid/coverage analysis in Velos eResearch and reporting to the billing entities.

  *NOTE: The Final Versions of the documents noted above must be received before the Coverage Analysis can be completely finalized.

COVERAGE TYPES

The following coverage types are the billing codes to be used on the billing grid for the coverage analysis:

- Invoice-R – Research event that must be invoiced to Sponsor or funding agency for payment.
- NB – Non-Billable – Event is not billable to funding sponsor or to third party payer.
- Q0 – Investigational item/service in Qualified Clinical Trial (QCT) reported to a third party payer. Must be billed with V70.7 diagnosis code, Q0 modifier and NCT# (ClinicalTrials.gov registration number).
- Q1 – Routine item/service in a Qualified Clinical Trial (QCT) billed to a third party payer. Must be billed with V70.7 diagnosis code, Q1 modifier and NCT# (ClinicalTrials.gov registration number).
- R – Research – Research charge being covered by Sponsor or funding agency, but does not require specific invoicing. May also include (ex. Informed Consent, Eligibility Criteria, Concomitant Medications, Medical History, Questionnaires, etc).
- SOC – Standard of Care - Conventional care procedure being charged as part of a non-qualified clinical trial to a third party payer; no additional codes or modifiers needed.

COVERAGE ANALYSIS INSTRUCTIONS

Using the determinations from the Billing Risk Questionnaire (BRQ), complete the following as required for studies with:

1) **No Billing Risk** – A coverage analysis is not required; no further action needed.

2) **Limited Billing Risk** – All clinical services are provided in a research environment without being entered into a billing system AND are paid for by the Sponsor or funding agency.
   a) Complete the billing grid/coverage analysis to include all services provided per the study plan (e.g., Protocol Schedule of Assessments/Events, Study Procedures, etc.).
      i) Complete the first column of the billing grid with all patient care costs related to the study
      ii) Complete the top row of the billing grid with the Visits and visit time points outlined in the Schedule.
      iii) Cross reference the Study Schedule with the Study Procedures to make sure the investigational product, as well as other drugs or devices appear in the billing grid/coverage analysis.
      iv) Review entire protocol. Items or services necessary for the coverage analysis may not be clearly identified in the procedures or schedule of events sections.
      v) Place an "X" in any box to indicate any item or service that is provided on that Visit.
   b) Compare the services listed on the billing grid with the funding agreement.

c) For each service provided, enter an "R" or "Invoice-R", as appropriate, to indicate that the cost is covered by the research funding agreement, ensuring that ALL services are truly covered by the agreement. If any services are still marked "X", provide the coverage analysis to the budget analysts for review and possible renegotiation with the Sponsor or funding agency. If unable to renegotiate, the study department will be responsible for such costs and should be marked with an "NB".

d) Instruct Research Team to maintain billing grid/coverage analysis for documentation purposes only. No further action required.

3) **Billing Risk** - A billing risk exists when clinical services are performed for a research study AND are entered into a patient billing system (ie. Epic, Sunrise/IDX, etc.). The Coverage Analysis requirements vary depending on funding and if the study is a Qualified Clinical Trial (QCT) or non-qualified. These determinations are found on the BRQ form. Coverage analysis requirements are as follows:

a) **All Services Paid by Funding Sponsor**

i) Repeat steps 2a under "Limited Billing Risk" above.

ii) Compare the services listed on the billing grid with the funding agreement.

iii) For each service provided, enter an "R" or "Invoice-R", as appropriate, to indicate that the cost is covered by the research funding agreement, ensuring that ALL services are truly covered by the agreement. If any services are still marked "X", provide the coverage analysis to the budget analysts for review and possible renegotiation with the Sponsor or funding agency. If unable to renegotiate, the study department will be responsible for such costs and should be marked with an "NB".

iv) Refer to "**Communication of Billing Instructions"** section below

b) **Some Services Paid by Funding Sponsor OR No Services Paid by Funding Sponsor**

i) Repeat steps in 2a under "Limited Billing Risk" above

ii) Compare the services listed on the billing grid with the funding agreement.

iii) For each service provided in the funding agreement, enter an "R" or "Invoice-R", as appropriate, to indicate that the cost is covered by the research. *(This step does not apply when no services are paid by a funding sponsor.)*

iv) For Qualified Clinical Trials (as determined by the Billing Risk Questionnaire)

(1) Mark the clinical trial study as "Qualified" in the appropriate location on the coverage analysis billing grid.

(2) Review remaining items/services to determine allowable billable costs, to include those that are:

(a) Typically provided absent a clinical trial (e.g., conventional care)

(b) Provided for diagnosis or prevention of complications

(c) Provided to monitor the effects of the investigational item or service

(d) Provision of the investigational item or service

(e) Investigational item/service itself, if necessary

(3) Mark with either Q0 (investigational item/service) or Q1 (routine care), as appropriate.

(4) Ensure that the NCT# (ClinicalTrials.gov registration number) is provided on the coverage analysis worksheet whenever a Q0 or Q1 is applied.

(5) Any remaining items/services are not allowable billable costs to Medicare or other third party payer, and must be billed to the research account. Provide the coverage analysis to the budget analysts for review and possible renegotiation with the Sponsor or funding agency. If unable to renegotiate, the study department will be responsible for such costs and should be marked with an "NB".

v) For Non-Qualified Clinical Trials (as determined by the Billing Risk Questionnaire)

(1) Mark the clinical trial study as "Non-Qualified" in the appropriate location on the coverage analysis billing grid.

(2) Review remaining items/services to determine ONLY those allowable billable costs that are typically provided absent a clinical trial and are for conventional care purposes only. Mark these with "SOC".

(3) Any remaining costs that are provided solely for study purposes (data collection, to determine trial eligibility, investigational item itself unless otherwise covered outside clinical trial) CANNOT be billed to Medicare or other third party payers and must be billed to the research account. Provide the coverage analysis to the budget analysts for review and possible renegotiation with the Sponsor or funding agency. If unable to renegotiate, the study department will be responsible for such costs and should be marked with an "NB".

vi) Refer to "**Communication of Billing Instructions"** section below

COMMUNICATION OF BILLING INSTRUCTIONS

Communication with the appropriate billing entities is crucial in preventing patients and/or their insurance carriers from being improperly billed for study services provided by the funding agreement or those that are not allowable costs. For these studies, the RABT** must be submitted to the appropriate billing entities (ex. UHS Research Dept, UTMedicine @ utmsaresearchbilling@uthscsa.edu, etc) as a means to communicate the billing instructions at the following time points:

a) Ensure the Study Information section is complete (including the billing grid/coverage analysis) and submit to create Research Study Account for billing the Research items back to the Study Site (copy primary research coordinator/contact).

b) Instruct the Research Team to:

   i) Complete and submit the Patient Information section as each participant is enrolled in the study so that the charges related to the study will be held for review.

   ii) Complete and submit the Service Information sections for each participant as the services occur, along with the date of service and other pertinent information. The billing entities will review this information to determine the responsible party for the charges (i.e. Research charges will be billed to the Research Account or to the third party payer as indicated on the RABT).

   **Refer to *Velos Work Instruction – Research Patient Billing* for instructions on communicating billing instructions to billing entities for those studies that are entered into Velos eResearch.

REFERENCES

CMS NCD 310.1 Clinical Trial Policy
Novitas Clinical Trials and Devices
HOP 7.7.1, Budgeting & Billing for Clinical Services Provided as Part of Research Involving Human Subjects
CTO Policy 1.3.2. Clinical Trial Billing