FM-701– Coverage Analysis

1. **PURPOSE:**
   The purpose of this policy is to describe the formal Coverage Analysis process used by UTRGV to ensure compliant clinical research billing in accordance with the Centers for Medicare and Medicaid Services Clinical Trial/Research Policy, NCD 310.1 and Medicare Claim Processing Manual, Chapter 32, Section 69.

2. **SCOPE:**
   The Coverage Analysis is applicable to all research projects involving human subjects, utilizing any facility, resource, employee, or faculty of UTRGV which may result in charges billed to a research account, a research participant, or a third-party health insurance carrier, regardless of the funding source.

3. **RELATED TERMS AND DEFINITIONS:**

Center for Medicare and Medicaid Services (CMS)
Clinical Trial/Research
Clinical Trial/Research Financial Analyst (CTFA)
Coverage Analysis Billing Matrix
Coverage Analysis (CA) Process
Current Procedural Terminology (CPT) Codes
Funding Source
Healthcare Common Procedure Coding System (HCPCS)
Investigational Device Exemption (IDE)
NCD 310.1: National Coverage Determination 310.1, CMS Clinical Trial/Research Policy and the basis of this policy and process.
Qualifying Clinical Trial/Research (QCT)
Routine Costs

Please reference the Standard Operating Procedures Glossary of Terms for complete definitions of terms in this SOP.

4. **POLICY STATEMENT:**
   The Coverage Analysis Process applies to all clinical research projects, regardless of funding source, involving human subjects generating billable charges for services, items, or space at the University of Texas Rio Grande Valley (UTRGV). This process aids in facilitating billing accuracy, mitigating billing compliance risk, and budget negotiations.

Before research services may be billed to a third-party health insurance carrier, the research project must meet the mandated qualifying criteria as outlined in the CMS Clinical Trial/Research Policy, NCD 310.1. When a research project is determined to be non-qualifying, research services may not be billed to a third-party health insurance carrier, and the research project will be expected to fund all services of the project.

Clinical research projects that do not comply with this policy will not be authorized to take place at any facility or utilize any staff or services of UTRGV for clinical research purposes. Any charges generated due to non-compliance with this policy are the exclusive responsibility of the study.

5. PROCEDURES:

5.1 Submission of Research for Coverage Analysis

- The Office of Clinical Research (OCR) is responsible for conducting the coverage analysis.
- The PI or a member of the study team will send an email to clinicalresearch@utrgv.edu with "Coverage Analysis Request" in the subject line.
- All study documents must be attached to the email. Coverage analysis cannot be completed without all study documentation. This includes, but is not limited to:
    - Protocol
    - Informed Consent(s)
    - All study manuals and guidance documents
    - Study budget – even if not finalized
- The email must also include the name of the Principal Investigator (PI) at UTRGV, study title, sponsor (if applicable) and IRB number, if already received.
- If the application to the IRB is still in progress, include the date submitted to the IRB in lieu of the IRB number.
- The Coverage Analyst will respond to the study team within three (3) business days with an estimated timeline for completion.

5.2 Coverage Analysis Qualification Form and Criteria – The Qualifying Clinical Trials Form is completed to determine and document a research project's qualifying status. To identify and bill a third-party health insurance carrier for routine costs associated with a clinical research project, the research must be determined qualifying based on the criteria of CMS Clinical Trial/Research Policy NCD 310.1. This includes conventional and standard of care services that would have been done regardless of the patients' research participation.

A qualifying Clinical Trial/Research Project must meet **all** three of the following:

1. The aim or purpose of the project must be an evaluation of an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The research must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

3. Research of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Research of diagnostic interventions may enroll healthy patients to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical research project for coverage of routine costs. Frequently referred to as the 3+1 Rule, in addition to all criteria being met in the above list, a Qualified Clinical Trial/Research Project must also meet **one** of the following criteria:

1. Study funded by the NIH, CDC, AHRQ, CMS, DOD, or VA.
2. Study supported by a center or cooperative group funded by the NIH, CDC, AHRQ, CMS, DOD, or VA.
3. Study conducted under an investigational new drug application (IND) reviewed by the FDA.
4. Study that is IND exempt under 21 CFR 312.2(b)(1).

In the event the project meets the first three criteria but does not meet one of the above four, the PI may be asked to complete and attest to the seven (7) desirable characteristics of a clinical research project as defined in CMS Clinical Trial/Research Policy. OCR will initiate the questionnaire form and work with centralized budgets and contracts teams who will seek completion from the PI. The seven (7) characteristics are:

1. The principal purpose of the research is to test whether the intervention potentially improves participants' health outcomes.
2. The research is well-supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
3. The research does not unjustifiably duplicate existing studies.
4. The research design is appropriate to answer the research question being asked in the research.
5. The research is sponsored by a credible organization or individual capable of executing the proposed research successfully.
6. The research is in compliance with Federal regulations relating to the protection of human subjects.
7. All aspects of the research are conducted according to appropriate standards of scientific integrity.

The qualification form must contain the following:

- National Clinical Trial Number or status towards obtaining one.
- The IDE or IND number when applicable.
- The date/version of the research protocol/plan on which the matrix is based.
- The identification of the research status (qualifying or non-qualifying).
- The number of active study arms and their names.
- The full name, department, and signature of the PI.

Routine Costs in a qualifying clinical research project include:

- Items or services that are typically provided absent a clinical research project (e.g., conventional care, standard of care).
- All items and services the payer would cover if the subject was not enrolled in a clinical research project.

- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item of service or the prevention of complications.
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, or for the diagnosis or treatment of complications.

Routine costs do not include:

- Items and services that are the investigational item or service itself, unless otherwise covered outside of the clinical research.
- Items and services provided solely to satisfy data collection and analysis needs not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan).
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the research project.
- Items and services provided in a non-qualifying research project.

5.3 Coverage Analysis (CA) Billing Matrix

The CA Billing Matrix identifies all clinical items or services associated with a clinical research project, including identification of the financially responsible payer for each service, such as the research project sponsor, other funding source, or a third-party health insurance carrier. The billing matrix is intended as a guide to use in determining which items and services are billable to a third-party health insurance carrier based upon the research protocol, informed consent, coverage determinations, coverage decisions, and federal guidelines. All items and services billed to a third-party health insurance carrier must be supported by medical necessity.

The Billing Matrix must contain the following:

- All time points that may occur within the study and the acceptable date range for each.
- The name or description of all billable services.
- The CPT and/or HCPCS code for all billable services
- The responsible financial payor of each service at each time point.
- Supporting justification for all services billable to a third-party health insurance payor.

The following is a listing of the approved billing designations and codes to be used in the billing matrix:

R – Research Charges. Charge is to be billed only to research account.

Q0 - Investigational clinical service provided in a qualifying research project. Charge is to be billed to the patient account, and a Q0 modifier will be added if required by billing policies or contracts.

Q1 Routine clinical service provided in an approved clinical research project. Charge is to be billed to the patient account, and Q1 modifier will be added if required by billing policies or contracts.

V(Q1) Patient-specific (PS) services that may or may not occur solely for research purposes during a time point in the research project. Billing determinations cannot be made until the service is scheduled. All PS items assigned to a coverage analysis must have a justification in the protocol indicating why the PS indicator is appropriate, and it must be documented in the comments sections of the coverage analysis. In the absence of clear indication, these charges will be assigned to the research project. If a determination is made that the service is billable to a participant or their third-party health insurance payor, medical necessity must be documented in the EMR.

NR Standard of care items mentioned in the protocol but not applicable to the Clinical Trial/Research Billing guidelines.

CL Lab testing that must be done at a central laboratory location as defined by the research protocol.

NB Services identified in the budget by the Research Administration and PI that do not result in a charge from UTRGV including administrative budget items.

5.4 Investigational Device Trial/Research

Device studies must comply with separate regulations related to Medicare coverage of devices (42 CFR 405.201-405.215 and 411.15 and 412.406). CMS relies on the FDA's approval category for Investigational Device Exemption (IDE) studies when making a coverage determination. Unlike non-device studies where the investigator/institution is responsible for confirming qualifying clinical research criteria, device studies must receive pre-approval from CMS for Medicare coverage of IDE studies. Instructions for seeking approval of Category A and B IDE studies can be found in Section 20.1 (C) of the Medicare Benefit Policy manual. While the approval process is different for an Investigational Device Trial/Research, the routine costs language of NCD 310.1 remains applicable to device research. Device related research projects are put through the Coverage Analysis Process to maintain compliant determination and billing practices.

Category A Devices are considered experimental/investigational where safety and effectiveness has not been resolved. The following applies to Category A Device research:

- CMS prior approval of the research project is required. This is initiated by the research sponsor.
- The device itself is not billable to a third-party health insurance carrier.
- Routine costs as identified in NCD 310.1 may be billed to a third-party health insurance carrier in CMS approved Category A Device research.

Category B Devices are considered non-experimental/investigational where the device safety and effectiveness has been resolved and has minimal risk. The following applies to Category B Device research:

- CMS prior approval of the research project is required. This is initiated by the research sponsor.
- The device may be billable to third-party health insurance carriers in a CMS approved research project.

- Routine costs as identified in NCD 310.1 may be billed to a third-party health insurance carrier in CMS approved Category B Device research.

5.5 Non-Qualifying, Non-Approved Clinical Research

Billing protocol-required services to a third-party health insurance payor in a non-qualifying clinical research project is prohibited. This includes services that would otherwise be considered routine costs in a qualifying research project and standard of care services that would be done regardless of the research project. If the service is required in the protocol and is determined to be non-qualifying, it may not be billed to a third-party health insurance carrier.

In the event a research project is found to be non-qualifying, OCR will facilitate a second opinion review. If it is confirmed the status was properly determined, OCR will work with the research team to see if there are steps that can be taken to bring the research project to a qualifying status.

Some suggestions that may be provided to the PI and study group to potentially attain qualifying status include but are not limited to:

- A request to the PI to re-review the QCT criteria.
- A request to the PI to complete and attest to the 7 desirable characteristics of the research as listed in the NCD 310.1 which may result in a determination that the research meets the qualifying criteria status.
- Review of the project objectives to determine if the wording or objectives may be changed to state therapeutic intent, when applicable.
- Review of the protocol, informed consent and all other study specific manuals to look at wording, intent of the study, and what services are required per the protocol. Consider possible revisions that may help certify the research as qualified.
- Determine all protocol services billable to the research study and give the study the option of paying for or establishing funds to pay for all services to be provided at UTRGV research rates.

5.6 Coverage Analysis Approval and Documentation

Upon completion of the CA process and documents, the completed documentation will be given to the PI for review and signature. It is the responsibility of the PI to bring forward any questions, change requests, or discrepancies in the documents to the coverage analysis team.

In the event there is a discrepancy or inconsistency in this process which cannot be resolved among the staff responsible for the process, the issue will be elevated within OCR.

Once all documentation is agreed upon, the PI will sign the final document(s) and return them to the coverage analysis team. These documents will be shared with the budgets and contracts teams. These documents should be maintained in a secure location within each department.

Amendments

OCR must be contacted when any change of protocol, budget, or informed consent takes place. OCR will determine if an amended Coverage Analysis is required and process it accordingly, going through all steps of a new research project.

6. REFERENCES

- CMS Clinical Trial Policy NCD 310.1
- CMS Medicare Claims Processing Manual, 32, 69.6
- CMS Clinical Trial Decision Memo CAG-00712R2

7. FORMS AND ATTACHMENTS

Coverage Analysis Qualifying Clinical Trials Form
Coverage Analysis Billing Matrix