RESEARCH BILLING PROCESS

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Research Billing Process Policy
Attachment 1: Medicare Qualifying Trial Determination
Attachment 2: Advance Beneficiary Notice Flowchart

Policy

Nebraska Medicine is committed to submitting charges for clinical research that are in full compliance with applicable federal laws, regulations and policies.

Purpose

To define procedures for identifying patients who are research subjects and to accurately charge medical procedure costs to a research payer, to a third party payer, or to a patient, as appropriate to maintain patient satisfaction and comply with federal laws, regulations and policies.

- This policy applies to all clinical trials conducted at Nebraska Medicine and University of Nebraska Medical Center (UNMC); including medical device trials (see Nebraska Medicine policy MI29 – Investigational Devices for specific medical device trial procedures and tools).
- This policy does not apply to dental clinical trials.

Definitions

Qualified Clinical Trials

Only qualified clinical trials are eligible for reimbursement for routine costs under Medicare. In order to be a qualified trial, the trial must meet three mandatory criteria and have other desirable characteristics using the Medicare Qualifying Clinical Trials Flowchart (Attachment 1)

Three mandatory criteria

- Trial evaluates an item or service that falls within a Medicare benefit category (e.g. physicians' service, durable medical equipment, diagnostic test) that is not statutorily excluded from coverage (e.g. cosmetic surgery, hearing aids);
- Trial has therapeutic intent.
  - To have therapeutic intent, the trial must, to some extent, assess the effect of the intervention on the patient outcome. The trial must not be designed to exclusively test for toxicity or disease pathophysiology; and
- Participants must be individuals with diagnosed disease rather than healthy volunteers, except for trials involving diagnostic intervention that require proper control groups.

**Seven desirable characteristics**

- The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes;
- The trial 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;
- The trial does not unjustly duplicate existing studies;
- The trial design is appropriate to answer the research question being asked in the trial;
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
- The trial is in compliance with federal regulations relating to the protection of human subjects;
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

**Deeming Criteria**

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by the Agency for Healthcare Research and Quality (AHRQ), in consultation with other agencies represented on the multiagency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry (ClinicalTrials.gov) for administrative purposes.

Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

- Trials funded by: NIH, CDC, AHRQ, CMS, DOD, or VA
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;
- Trials conducted under an investigational new drug application (IND) reviewed by the FDA; or
- Drug Trials that are exempt from having an IND number under 21 CFR 312.2(b)(1) will be deemed automatically qualified until qualifying criteria are developed and the certification process is in place. At that time, the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

**Routine Costs**

Routine costs of a clinical trial include all items and services that otherwise would be generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or control arm of a clinical trial.

Routine costs in clinical trials include:

- Items or services typically provided absent a clinical trial (i.e. conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g. administration of a covered chemotherapeutic agent);
- The clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service – in particular, for the diagnosis or treatment of complications.
Research Costs

Patient care costs associated with the research trial.

Examples of items and services that are specifically included as research costs are:

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

PROCEDURE:

1. Responsibilities:

   The Principal Investigator (PI) and his/her designees are responsible for:
   a. Submitting new IRB Studies via the Study Intake process using the study intake form found on the VCR website VCR Study Intake Form or the CTMS website Clinical Trials Management System. Completion of the form will generate an email to Clinical Trials Management System, studyintake@unmc.edu, UNeHealth and Sponsored Programs Administration.
   b. Completing required documentation to support charges for each research subject, including creation and maintenance of the Clinical Trials Master Matrix for studies open to enrollment prior to activation of the Clinical Trials Management System (CTMS).
   c. Internal forms in ADIS must be completed prior to enrolling patients into the study.
   d. Verifying study build in One Chart is active and the CTMS is open to enrollment prior to enrolling patients. Once consent has been obtained the One Chart Patient Research Enrollment activity must be updated to reflect study participation to allow for future services to be linked to the study.
   e. The One Chart Linking activity of associating an order to research and linking an encounter is required to make certain technical and professional billable items are accurately charged to the grant, the third party payer, or to the research subject.
   f. Informing the research subject of the billable items and how they will be allocated as a part of the informed consent process.

2. Clinical Trial Matrix Workbook:

   The Principal Investigator/Clinical Research Coordinator/designee shall use the following tools to identify and accurately charge research related tests, exams, and procedures:
   a. Clinical Trial Master Matrix – Required – Lists all clinical trial-related technical and professional charges, and whether the charges will be billed to the grant, the third party payer, or to the research subject as standard of care.
   b. Subject List – Required – This page lists all research subjects approached for the study and their status (screen fail, enrolled, etc.), their visit dates and if there were exceptions to the usual billing. If there were deviations from the matrix that would change the billing, indicate “YES” in the “exceptions” column and add appropriate information under the tab marked “Exceptions List”.
   c. Exceptions List – Required – This helps track anything unusual that may have occurred in the visit. List procedures/treatments/tests that should have happened according to the matrix that did not occur or additional procedures/treatments/tests that were done and were not listed on the matrix. Complete the form including the patient number, visit number and date as well as what had changed. This must be completed within 24 hours (1 business day) but not to exceed 48 hours (2 business days) of the visit.
   d. Individual Subject Matrix – Optional - This lists each research subject and the dates of their visits. This is a valuable tool in tracking the billing on individual patients and can be re-formatted in a way that coordinators find most helpful.
   e. Invoicable Items – Optional – If there are billable items that are not accounted for in the “per visit”
payment or an unscheduled visit that requires an invoice to enable payment. – Indicate “YES” on the subject page in the “Invoicable items” column and go to the Invoicable items page and capture the patient name, visit number, and date with a description of what must be invoiced.

f. Medicare Qualifying – Drug – Required page for drug trials – Indicate the criteria that qualifies the trial for Medicare qualifying status. Study specific additional details provided within separate Coverage Analysis requirement.

g. Medicare Qualifying – Device – Required page for device trials – Supply device information and answer the questions included on the tab within the Clinical Trial Matrix workbook. Study specific additional details provided within separate Coverage Analysis requirement.

You must have training on the maintenance of the matrix before you can gain access to the Clinical Trials folder. The Research Billing Compliance Lead in the Clinical Research Center provides training on the Clinical Trial Matrix Workbook.

3. Clinical Trials Management System (CTMS)

The Principal Investigator/Clinical Research Coordinator/designee shall use the CTMS to identify and accurately charge research related tests, exams, and procedures:

a. Must complete required CTMS training to allow for access to manage required study documentation including patient visit information.

   • To gain training and access to the CTMS contact CTMS@nebraskamed.com. Registration for training class can be accessed through Nebraska Medicine Apollo Resource Center Class Options are listed below:

   o Clinical Trials Management System – ALL ROLES
   o Clinical Trial Management System
   o Clinical Trial Management System – FINANCES

   • Clinical Trial Management System – SUBJECT MANAGEMENT The CRA Console allows access to subject registrations, demographics, consent form details, and details regarding individual subject visits. It also provides an overview of similar information for all subjects on a protocol. The various pages (tabs) within the CRA console allow you to view subject information from a protocol perspective.

The Principal Investigator/Clinical Research Coordinator/designee shall create a folder on the NHSsecuredrive>Clinical Trials> Department for each clinical trial, and place the billing grid used for Insurance Pre-determination in the appropriate specialty/departmental folder, listed by IRB#, Funding Source # and Study pet name. List all grants (WBS#, MXH#, and/or CC# when available).

Note: Regardless of source of visit documentation (Clinical Trials Matrix Workbook or the Clinical Trials Management System), the research subject visit information must be updated within 24 hours (1 business day) but not to exceed 48 hours (2 business days) from the date of service for each clinical trial visit

4. Research Subject Informed Consent:

The Individual obtaining informed consent from the subject shall review the charges with the patient so that they understand how the charges will be billed and what charges they are or potentially may be responsible for paying. The research subjects shall be informed that they will be responsible for paying any balances due after insurance has paid for routine care.

The original informed consent shall be placed in the research file. A copy of the consent shall be scanned into the medical record, and a copy shall be provided to the research subject pursuant to IRB and hospital policies.

   a. Advance Beneficiary Notice Requirements for Research Subjects who are Medicare Beneficiaries. If the research subject is a Medicare beneficiary, and the clinical trial the subject is participating in does not meet the criteria for a Medicare Qualifying Trial (see Medicare Qualifying Clinical Trials Flowsheet), then the individual obtaining informed consent must
provide the research subject with an Advanced Beneficiary Notice (ABN).

The ABN is a written notice instructing the subject that Medicare may deny payment for a specific service or item; specifies the reason the provider expects Medicare to deny payment, and that the subject will be personally and fully responsible for payment if Medicare denies payment. The ABN provides the subject with the opportunity to refuse to receive the service or item.

See Nebraska Medicine Policy MI15, “Advanced Beneficiary Notice (ABN) for guidance on obtaining the ABN. See also the Advanced Beneficiary Notice Requirements Flowchart, which provides additional information.

Note: The research subject cannot be charged for any research – related items or service that Medicare does not cover if an ABN is not signed.

b. Insurance Pre-authorization – In the case that a patient is participating in a clinical trial and items are determined billable to their insurance the process for insurance pre-authorization utilizing Patient Financial Services should be followed. This is done to insure that all attempts have been made to work with the participant’s insurance provider to determine coverage and the participant is fully aware of all financial responsibilities if they enroll in the study. Forms can be found at:

Clinical Trial Insurance Predetermination Request Form
(https://unmc.edu/ccfr/_documents/predetermination-request-form.docx) and the
Nebraska Medicine SOP 201.2 Insurance Predetermination Form
(https://unmc.edu/ccfr/_documents/Insurance-Predetermination-SOP-signed.pdf)

5. Creating Medical Record:

Creating Medical Record in One Chart – A research subject must be registered in One Chart to be able to schedule the patient. If they are not registered, submit the information to Access Services to establish the medical record (Nebraska Medicine Policy and Procedure RI06 Admission/Registration to Nebraska Medicine and ACCESS-REGSP-110)

6. Building a Study in One Chart:

Prior to the study starting the billable items will have to be “built” into the “administrative study record” in One Chart. This will set the system up so the study charges will route to the appropriate accounts. This involves the PI/Coordinator/designee submitting the “research study matrix” to the Clinical Research Advisor. All required information is included in the current version of the master matrix template.

7. Enrolling a Patient in One Chart:

Once a patient agrees to participate in the study, they must be enrolled in One Chart. This will make it possible to link the study visits later. Patient enrollment education is part of mandatory training. Enrollment is in One Chart Research in Apollo (Nebraska Medicine). Please refer to the study guide for a quick reference if needed.

8. Linking a study visit in One Chart:

The study participant’s encounter and orders must be linked to your study to allow One Chart system functions to sort the billable items. Appropriate charges will route to the patient’s Personal/Family account and/or the grant account. Only the charges that you placed into the administrative record should sort into the grant account. The other charges should sort into the Personal/Family account. The Research Billing Sr. Associate will review all of the charges and compare them to the updated matrix, move charges that are in the wrong accounts and then release them. It is imperative and required that the matrix is kept current per patient visit.
9. Ending Participant Enrollment in One Chart:

Once a study participant is no longer actively participating in the research study the coordinator must change their status to “complete” or “withdrawn” within 2 months, whichever is most accurate.

10. Ending the Study in One Chart:

When enrollment is complete, and all study visits have occurred, and the billing for all patients is resolved, the study can be ended by contacting the One Chart Clinical Informatics Lead.

11. Billing Compliance

Documentation from Research Coordinators and/or other research personnel is required to be completed within 24 hours (1 business day) but not to exceed 48 hours (2 business days) from the date of service rendered. If documentation is not provided, the Research Billing Sr. Associate will contact the coordinator for directions. If the coordinator is unwilling or unable to comply, his/her supervisor and the investigator will be notified so that they can update the matrices.

Grant itemized statements are available in One Chart and can be found by using the Tips and Tricks for looking up Grant charges (Looking up Grant Charges on Statements – One Chart Resources).

Statements shall be reviewed monthly to verify that only study pay billable items are reflected on the grant account. Contact the Research Billing Compliance Lead or Research Billing Sr. Associate if there are billing errors.

12. One Chart Research

All individuals responsible for placing clinical research orders and charging related costs shall complete the mandatory One Chart Research course. Enrollment is in Apollo (Nebraska Medicine). Additional clinical research billing education may be provided by the Clinical Research Center as needed.

The Nebraska Medical Center Related Policies:
IM41: One Chart Research Documentation

STAFF ACCOUNTABILITY
Internal Audit and Compliance (3/2016, 4/6/2018)
Associate Vice Chancellor for Research

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<tr>
<td>Signed: LuAnn Larson, RN, BSN</td>
<td>Signed: Matthew Lunning, DO</td>
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