Nebraska Medicine POLICIES AND PROCEDURES MANUAL ☒ System ☐ Department Supersedes: FN9; UNMCP- CD20	Section: MISCELLANEOUS ORGANIZATIONAL FUNCTIONS (MI) Subject: Research Billing Process Number: MI19 Attachments: Attachment 1 Medicare Qualifying Trial Determination; Attachment 2 Advanced Beneficiary Notice; Attachment 3 Looking up Statements in One Chart Date Effective: 6/05/00, 5/15/03 Date Reviewed: 11/30/05, 07/01/2010, 8/31/12, 10/23/13, 11/23/15, 2/15/16, 3/6/18, 3/6/20, 3/1/22, 3/10/23, 10/30/2024

RESEARCH BILLING PROCESS

Index
Research Billing Process Policy

Attachment 1: Medicare Qualifying Trial Determination
Attachment 2: Advance Beneficiary Notice
Attachment 3: Looking up Statements in One Chart

Policy
This policy establishes steps to ensure that research billing is completed accurately, timely and in accordance with the guidelines of Medicare NCD (National Coverage Determination) 310.1 and institutional policies.

Purpose
To define the process to be followed and the parties responsible.

DEFINITIONS

Research Study Administration Record (RSH) – This is the research study record in One Chart containing information about the study, including the PI (Principal Investigator), coordinator, study description, funding source, and billing setup.

Clinical Trials Management System (CTMS) – This is the system that UNMC/Nebraska Medicine uses to support research functions on campus. This application supports the management of therapeutic protocols and subjects. The CTMS allows administrative, regulatory, financial, and clinical functions to interact in a centralized area.

Retrieve Process for Execution (RPE) - This refers to the interface from CTMS to One Chart. When a study is open to accrual in the CTMS, it is then pushed to One Chart. Study status updates such as screening, enrolled, withdrawn, ineligible, and completed are also pushed to One Chart via RPE.

Qualified Clinical Trials (QCT) - This is a trial that meets the requirements set forth in the Clinical Trial Policy (NCD 310.1) by the Center for Medicare and Medicaid Service (CMS).

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.

Research Costs - Patient care costs associated with the research trial.

Advance Beneficiary Notice (ABN) - The Advance Beneficiary Notice of Noncoverage (ABN) is issued by providers, physicians, practitioners, and suppliers to Medicare beneficiaries when Medicare payment is expected to be denied. The ABN is issued to transfer potential financial liability to the Medicare beneficiary in certain instances.

Insurance Pre-authorization- This term is often used interchangeably with pre-determination. Per Nebraska Medicine Policy FNC–201 and Affordable Care Act (ACA) – Section 2709, pre–authorization is no longer required for all trials except investigational device trials. Investigational device trials will still require review by the Investigational Device Review Committee.

Designated individuals will be responsible for the following:

- The Principal Investigator or designated staff (Clinical Research Coordinator, Clinical Research Assistant, Data Coordinator) are responsible for ensuring all research orders and encounters are linked to the research study in One Chart. It is imperative and required that accurate and timely documentation of research subject visit information (visits, tests, exams, procedures) is updated in the CTMS or Matrix within 48 hours from the date of service. When documentation is not updated within this timeframe, a Research Billing Compliance Information Request form will be generated to the study team. Failure to comply may result in the study being charged for any unrouted charges.
- As part of the process of obtaining informed consent from a potential subject, it will be discussed by the consenting individuals that events occurring during the conduct of the research may generate a bill that they may be responsible for paying. The research subjects shall also be informed that they will be responsible for paying any balances due after insurance has paid for routine care. If an ABN will be utilized, this should be reviewed and signed. The original informed consent and signed ABN shall be placed in the research file. A copy of the consent and ABN shall be scanned into the medical record, and a copy shall be provided to the research subject pursuant to IRB (Institutional Review Board) and hospital policies.
- Using CTMS or Matrices, CRC Research Biller will correctly identify research charges and routine charges and route the research-related charges accurately and timely to the study or third-party payor. If the subject visit information is not up-to-date and CRC Research Biller cannot route charges, a Research Billing Compliance Information Request form will be generated for the study team to update the missing information.

PROCEDURE:

1. Billing Grid
    a. Clinical Trials Analyst (CTA) will submit a ticket to CTMS for Billing Calendar to be built.
    b. A preliminary billing grid will be provided by CTA to CTMS, Department, and Research Billing.
    c. Billing Calendar is built in CTMS by CTMS group.
    d. Protocol sign offs occur in CTMS, and the study is opened to accrual.
    e. Study is pushed to One Chart via RPE.

2. One Chart Analyst will build the study in One Chart to include NCT # and WBS #.

3. Principal Investigator, Research Coordinator, or the designated individual is responsible for the following:
    a. Enrolling the patient in the study in CTMS which then pushes the information to One Chart via RPE.
    b. Scan or email the signed Informed Consent Form to Health Information Management at HIMImaging@univnebrmedcntr.mail.onmicrosoft.com within 24 hours.
    c. Linking all orders, scheduled visits, and admissions to the research study and appending the research diagnosis of Z00.6.
    d. Updating the subject visit information with correct dates in CTMS or Matrix within 48 hours.

4. CRC (Clinical Research Center) Research Biller will perform the following functions:
    a. Using the Research Billing Review activity - Review the patient account linked to research against CTMS or Matrix.
    b. Verify that research identifiers are appropriately appended to Medicare claims. (dx Z00.6, mods Q0 or Q1).
    c. Route charges to P/F guarantor or to the study guarantor.
    d. Research accounts are exported from One Chart in Excel format to include study name, account number, and funding source number and forwarded to PFS Billers.
    e. Research MXH accounts are exported from One Chart in Excel format to include study name, account number, and MXH number and forwarded to PFS to be written off.

5. PFS Biller will assist in the research billing process by:
    a. Attaching a coversheet to the monthly grant billing excel document and forward to SPA (Sponsored Programs Accounting) for processing.
    b. Manual adjustment or a write-off of MXH accounts listed on the monthly MXH spreadsheet.
    c. Allocating research payments issued by SPA to research accounts in One Chart.

6. Sponsored Programs Accounting will assist the research billing process by:

a. Moving monthly research statements produced by One Chart to Clinical Research Folders.
b. Issuing WBS payments to Nebraska Medicine for posting in One Chart.

GENERAL INFORMATION:

- CTMS training is required to gain access to the CTMS. Please contact the CTMS team at CTMS@nebraskamed.com.
- Individuals responsible for placing clinical research orders must complete the mandatory One Chart Research course. Enrollment is in Apollo (Nebraska Medicine).
- Research statements are to be reviewed monthly by research staff to verify that only study pay billable items are reflected on the grant account. Contact ResearchBilling@unmc.edu if there are billing errors. Any errors on statements should be reported no later than 30 days from the date the statement is issued.
- Automated research study statements (HB and PB) are produced on the 15th of the month in One Chart.
- All surgeries, scans, drugs, and other procedures that require pre-authorization will be done by PFS. It is important to note that many insurance companies require at least 7-15 days to process and grant a prior authorization. Insurance pre-authorization is part of Nebraska Medicines' standard procedure that occurs for all patients regardless of research enrollment and is intended to reduce the financial burden for all parties.
- To comply with all research billing state and federal laws and institutional policies, CTAs will require all necessary documents from the sponsor before developing a coverage analysis for new study and amendment. CTA must have preliminary complete coverage analysis prior to enrollment in a new arm/cohort; however, the study team/PI will assume financial liability for enrolling in a new arm/cohort before the final release in CTMS. These instances will be reviewed on an individual study basis.

The Nebraska Medical Center Related Policies:
IM41: One Chart Research Documentation
MI15: Advance Beneficiary Notice (ABN)
MI29: Investigational Devices
DEN001: Timely Billing
DEN007: AUTH Doc Type

STAFF ACCOUNTABILITY
Administrator of Clinical Research Center (11/30/05, 7/1/2010, 8/31/2012, 11/23/2015, 2/15/16, 3/6/18, 3/6/20, 3/1/22, 3/10/23, 10/30/24)
Internal Audit and Compliance (3/2016, 4/6/2018, 3/1/2022)
Assistant Vice Chancellor for Clinical Research

Department Approval	**Administrative Approval**
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Title: Administrator	Title: Assistant Vice Chancellor for Clinical Research– Clinical Research Center
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