

Part VIII: Coding and Documentation

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As required by Allina policy and government billing regulations, a patient's participation in a clinical trial must be documented in the medical record. Documentation within the medical record substantiates:
1) whether the item or service was medically reasonable and necessary, and 2) whether the service can be billed to a third party payer.

Documentation

It is important to document the purpose of the research-related item or service in the medical record. When an item or service changes from being non-billable to billable, it is essential that the medical record documentation supports this change. A simple statement explaining this change is required.

Example: A cancer patient participating in a clinical trial is expected to receive a CT scan at six months as routine care. The clinical trial requires that a CT scan be done at three months for data collection only. This service is shown on the PIC Worksheet as a PIC. During the three-month visit the patient shows additional symptoms so a CT Scan is required to determine the extent of the cancer. Although the CT scan was originally determined to be a PIC on the PIC Worksheet, it has become a billable service because it is required to treat the patient (it is routine care).

Research Orders

It is the responsibility of the research site to properly document care provided as part of a research project. SPA and Allina Internal Audit staff uses the documentation for monitoring and auditing purposes. It is very important to document clearly within the medical record when items and services are considered routine care but appear on the PIC Worksheet as protocol-induced. Lack of clarity can result in items being determined to be errors and billed back to the research site.

To provide proper documentation of research services within the medical record, write "research" or "for research" next to the services ordered as protocol-induced costs. Providing this documentation helps during the auditing and monitoring process.

Research Order Form

In order to facilitate and further clarify research orders from routine care, SPA **strongly** recommends the use of a Research Order Form for participants who are receiving services within Allina. A Research Order Form (ROF) creates ease for the physician by having the research orders pre-printed, as well as aids in distinguishing research orders from routine care orders for monitoring and auditing purposes.

SPA created a ROF that can be used to generate these orders (available on the disk provided by SPA). In addition, a research site may create their own form provided it looks similar, and contains the same elements as Allina SPA's form. The ROF, or its equivalent, are physician orders and will be subject to the same rules of proper ordering and charting, as dictated by Allina, for standard physician orders (i.e., dated, signed, corrections initialed). The entire procedure for the use of this form is outlined in Research Procedure 312.00, "Research Orders Procedure."

How to Complete the Research Order Form

Study Name - Enter the name of the study—either using the long name, the protocol number or a short name.

Contact Person - Enter the name of the individual who should be contacted regarding the form, participant or study.

Phone - Enter the contact person's phone or pager number.

Research Plan Code - Enter the Research Plan Code given to the research site. The Research Plan Code (RPC) is in lieu of having to enter the research site's name.

Guidelines for entering text into the body of the ROF.

- Using the lines, or computer template, list the research services that will be performed during the hospital visit. Only the services required during the visit should be entered. In other words, you may only include the services from the schedule of events that will be performed on the current hospital admission.
- Items and services listed on the ROF should be marked as either routine care or protocol-induced cost (PIC). This designation can be reversed should the items or services change from protocol-induced cost to routine care or vice versa.
- If an item or service changes from protocol-induced cost to routine care, it must be documented on the ROF.
- If the ROF is used in conjunction with regular standing orders, we recommend the following:
 - If both sets of orders match as being routine care, the ROF item or service may be crossed out, providing it is appropriate from a billing perspective.
 - Cross out an item or service that is not provided on the ROF.
- The ROF must be signed by the physician or other appropriate person as determined by the Allina facility. Standard charting policies, as dictated by Allina, apply to all research orders.



Instructions:

- This form must be completed in its entirety by Research Site.
- This form follows all procedures related to Physician Orders and must be signed according to hospital policy.
- This form should be placed in the physician order section of the medical record.

Study Name _____

Contact Person _____ Phone _____

Research Plan Code (RPC) _____

Sample

RESEARCH ORDER FORM ~ DO NOT DISCARD

Physician's Signature

Date



ALLINA
Hospitals & Clinics

**RESEARCH ORDER FORM
DO NOT DISCARD**

MMC #400d
A10064 (12/03)
Reviewed 8/04

PATIENT LABEL

Coding

Coding began as a way to track disease and has evolved into a complex system for health care billing. Coding is the process of assigning numerical codes to the items and services provided to the patient as a means of transferring the information in the medical record to substantiate payment to providers.

Coding (for the purposes of this Guide) is the act of placing diagnoses and procedure codes (e.g., CPT, HCPCS, etc.) on the items and services furnished to a participant in a clinical trial.

Coders are trained in the various aspects of disease and in applying the correct diagnosis and CPT codes to a bill for submission to a third party payer. Coders are required to evaluate the information contained within the medical record in order to apply the correct set of codes. Sometimes, coders must contact the physician in order to obtain the correct information.

What will the Coder do?

A Coder will review all documentation surrounding the visit and apply the correct codes for the service. Some of the information reviewed includes:

- The Research Service Form, if applicable
- The admission summary
- The progress notes or written orders
- Test results
- The medical record
- The discharge summary

The NCD and Coding

The NCD identifies the specific coding requirements for Medicare participants enrolled in qualifying clinical trials.

Research-related items and services are billed on the following claim forms:

Coding for Items and Services Billed on the HCFA-1500 or “Professional Services”

The basis for the coding requirements of the NCD is stated in “Medicare Coverage Policy ~ Clinical Trials Provider Bulletin” (located in Part II of this Guide) and other guidance from CMS. A recent update from CMS, Program Transmittal AB-01-142 (also located in Part II), updated the requirements of the NCD and should be used. The following appears in Program Transmittal AB-01-142:

“Effective for services furnished on or after January 1, 2002, HCFA 1500, or electronic equivalent, billers will use the procedure code modifier “QV” to identify and report routine care for Medicare qualifying clinical trial services. The reporting of diagnosis code V70.7 as a secondary diagnosis on HCFA-1500 (or the electronic claim equivalent) will no longer be required for dates of service on or after January 1, 2002. For dates of service on or after January 1, 2002, the QV modifier constitutes the billers attestation that a service, supply, or equipment meets the Medicare qualifying coverage criteria for clinical trial services processed by carriers and DMERCS.”

Exception: Routine care clinical trial services furnished on or after January 1, 2002 to healthy, control group volunteers participating in Medicare qualifying diagnostic clinical trials are to be coded and billed in the following manner:

- The “QV” procedure code modifier is reported at the line item level.
- Diagnosis code V70.7 (examination of participant in clinical trial) is reported as the primary diagnosis for applicable line items on the HCFA-1500 or electronic claim equivalent.
- If diagnosis code V70.7 is reported as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a healthy control group, diagnostic trial volunteer.

Coding for Items and Services billed on the HCFA 1450 or UB-92

The basis for the coding requirements of the NCD is stated in “Medicare Coverage Policy ~ Clinical Trials Provider Bulletin” (located in Part II, “Billing Guide” of this Guide) and other guidance from CMS. A recent update from CMS, Program Transmittal AB-01-142, updated the requirements of the NCD and should be used. The following appears in Program Transmittal AB-01-142:

“For inpatient discharges and all other intermediary and RHHI processed services occurring on or after January 1, 2002, routine care for Medicare qualifying clinical trial services must be identified with diagnosis code V70.7 (examination of participant in clinical trial). V70.7 is reported as the second or subsequent diagnosis code (generally the third or subsequent diagnosis for HHAs) on the HCFA-1450 or electronic claim equivalent.”

Research Service Form

Allina SPA created a Research Service Form (RSF) to communicate to coding personnel the patient is a Medicare participant in a qualified clinical trial, or the patient is enrolled in a trial that meets the Minnesota Cancer Clinical Trial Voluntary Agreement. The RSF will provide the necessary documentation to support adding the appropriate diagnostic code and modifier to the patient’s bill(s). The RSF also provides a mechanism for documenting the trial name, sponsor, and protocol number; and advising coders of additional codes to be attached to the bill.

The RSF is used by the research site to schedule services for participants in qualifying clinical trials and to provide the source of documentation for coders to support the placement of diagnosis code (V70.7) and the QV modifier, if applicable.

The following information must be included in the medical record of Medicare clinical trial participants:

- Trial name
- Sponsor
- Protocol Number
- Informed Consent Document must be readily available.

Note: *A copy of the signed, participant informed consent form, approved by the IRB, must be included in the medical record or readily available upon request.*

The section in the box below appears on the RSF. By submitting the RSF at the time the research services are rendered, the research site communicates to the coding department the patient falls into one of the following categories and the V70.7 diagnosis code should be applied to the service:

- Medicare patient enrolled in a qualified clinical trial
- Patient enrolled in a trial that meets the Minnesota Cancer Clinical Trial Voluntary Agreement

Coding Documentation

Assign the research diagnosis code V70.7 to the patient account. It has been determined this clinical trial meets the qualifying criteria, as required by the National Coverage Decision (NCD) for Medicare Coverage of Clinical Trials or the Minnesota Cancer Clinical Trial Voluntary Agreement.

Completing the Research Service Form

Inpatient

- Follow the guidance in Part VII, “Research Plan Code” of this Guide for instructions on how to use the Research Plan Code.
- If a Medicare patient is participating in a trial that meets the qualifying status of the NCD, or if the patient is enrolled in a trial that meets the Minnesota Cancer Clinical Trial Voluntary Agreement, the research site should complete the RSF and place it in the consent/authorization section of the patients medical record prior to discharge.
- If the patient is participating in a trial that does not meet the qualifying status of the NCD, do not use the RSF.

Outpatient

- Follow the guidance in Part VII, “Research Plan Code” of this Guide for instructions on how to use the Research Plan Code.
- If a Medicare patient is participating in a trial that meets the qualifying status of the NCD, or if the patient is enrolled in a trial that meets the Minnesota Cancer Clinical Trial Voluntary Agreement, the research site should complete the RSF and forward the completed form to each department performing a service prior to the patients departure.
- If the patient is participating in a trial that does not meet the qualifying status of the NCD, do not use the RSF.

Additional Forms

If a research site is in need of additional forms, they should contact:

Allina Sponsored Projects Administration

spa@allina.com

612-262-4926

Provide the following information:

- the form you are requesting,
- the number of forms you would like, and
- the address to deliver the forms to.

There will be a charge to the research site.

You may also photocopy and punch the forms as necessary

Instructions: This form must be completed in its entirety by Research Personnel for

- Medicare patients enrolled in a qualifying clinical trial
- Patients enrolled in a trial that meets the Minnesota Cancer Clinical Trial Voluntary Agreement

Outpatient research services:

1. Complete this form when scheduling outpatient research services for study participants.
2. Forward the completed form to each department performing the service **prior** to the patient's appointment.
3. This form must be in the medical record prior to patient discharge (patient leaves the facility).

Inpatient research services:

1. Complete this form once per patient hospitalization when research services are performed.
2. Place this form in the consent/authorization section of the patient chart immediately upon admission or enrollment into a research study. This form must be in the medical record prior to patient discharge.

Coding Documentation

Assign the research diagnosis code V70.7 to the patient account. It has been determined this clinical trial meets the qualifying criteria, as required by the National Coverage Decision (NCD) for Medicare Coverage of Clinical Trials or the Minnesota Cancer Clinical Trial Voluntary Agreement.

Patient's Name _____ Date of Birth _____

Male Female Social Security Number _____

Referring Physician _____

Complete Trial Name _____

Sponsor Name _____

Protocol # _____

Study Contact _____

Phone _____ Fax _____

RESEARCH SERVICE FORM



RESEARCH SERVICE FORM

ALLINA
Hospitals & Clinics

MMMC #485a
A10004 (12/01)
Revised 10/03; 8/04

PATIENT LABEL

Using the Research Plan Code for Complications

Coding for complications will follow the same process as coding billable and non-billable items and services. Review the algorithms in Part II, “Billing Guidance,” for assistance in making the distinction between billable and non-billable services. As discussed in Part II, “Billing Guidance,” complications are divided into two categories: expected and unexpected.

Expected Complication is a pathological process or event that is typical for the disease or described within the protocol. For example, it is typical that a patient receiving chemotherapy will have nausea. Expected complications are billable if the trial is deemed, otherwise, generally non-billable. Refer to the “Medicare Outpatient Self-Administered Drug” or “Clinical Trials for which no Reimbursement is Allowed” Algorithms (Part II) to determine whether the complication is billable.

Unexpected Complication is a pathological process or event that is not typical or described in the protocol. For example, a person taking a heart medication gets pneumonia. Unexpected complications are generally covered. Refer to the “Medicare Outpatient Self-Administered Drug” or “Clinical Trials for which no Reimbursement is Allowed” Algorithms (Part II) to determine whether the complication is billable.

Note: *Depending on the outcome using the criteria presented below, the research site may need to contact Registration to have the Research Plan Code added to the participant’s account.*

Qualifying Trial

If a trial qualifies under the NCD, an expected or unexpected complication is billable and is subject to all other rules of the NCD and Medicare Regulations.

Plan Code Usage

If the trial is deemed to qualify, the research site must use its Research Plan Code according to instructions presented in Part VII, “Plan Code Usage” of this Guide with respect to billable and non-billable charges.

Medical Record

- Use the Research Service Form for Medicare participants, or for patients enrolled in a trial that meets the Minnesota Cancer Clinical Trial Voluntary Agreement.
- The physician should document any pertinent information he or she normally records in the management of the patient or participant.

Non-qualifying Trial

If a trial does not qualify under the NCD and a complication occurs, use the following guidelines when using the Research Plan Code and documenting the item or service. Generally, expected complications are not billable for non-qualifying trials. Please refer to Part II, “Billing Guidance” for additional help.

Expected Complication

Plan Code

If the complication is expected, the research site should use the Research Plan Code.

Note: *The research site should contact SPA (612-262-4926 or 612-262-4927) in order to make arrangements for payment. The research site is financially responsible for complications that are expected and should take appropriate steps to ensure that its Written Agreement with the sponsor addresses paying for complications.*

Medical Record

The physician should document any pertinent information he or she normally records in the management of the patient or participant.

Unexpected Complication

Plan Code

If the complication is unexpected, DO NOT use any Research Plan Code. These items and services are typically billable.

Medical Record

In a non-qualifying trial, unexpected complications are billable. The physician should document any pertinent information he or she normally records in the management of the patient or participant.

Research Patient Type (RPA)

Abbott Northwestern Hospital Only

Purpose

Abbott Northwestern Hospital (Abbott) provides research services to many clinics on an *outpatient* basis. There are times during a research study when a test or service is needed and the results or sample (e.g., blood) must be sent directly to the research sponsor (e.g., blind studies). When this occurs, no “official” documentation is created to be placed in the medical record. This causes the patient account to be placed in coding limbo waiting to be coded (application of CPT or ICD-9 codes, etc.) and a backlog of accounts waiting for coding staff to search for reports that do not exist.

In order to solve this problem, Abbott has designed the patient type “RPA” for those research services that do not generate a report. It will also assist with chart management in medical records, allowing staff to see that a service has been provided but that there will be no report from which to code or bill. The following describes how and when to use the patient type RPA.

Patient Type – a set of characters that allow certain services performed within an Allina facility to convey certain information to the staff or information systems.

RPA – a patient type designed specifically for Abbott to identify an outpatient research service for which no report is generated, no third party billing occurs, and no “official” medical report exists.

RPA Requirements for Use (*all must be met*):

- The outpatient service is performed at Abbott.
- No report or result is generated for the medical record—information is sent directly to research sponsor.
- No third party billing is done.

The Research Site will:

- contact the scheduling or registration staff to schedule a service for a research participant;
- inform the scheduling or registration staff to use the RPA patient type; and
- provide the research site’s Research Plan Code (refer to Part VI of the Guide).

Scheduling and Registration Staff will:

- use the RPA patient type for the requested service as instructed by the research site;
- use the Research Plan Code (D##) provided by the research site;
- enter the following information into the comment field when scheduling a patient: “Research Patient-RPA/D##”; and
- use extra caution when keying the RPA patient type—this cannot be changed or modified later.

Please note:

- For research outpatients, **both** the RPA (patient type) and the Research Plan Code are required.
- Accuracy in entering the RPA patient type is very important because it is restricted in the STAR system (it is similar to the RLA patient type used by the Allina Lab).
- The charges interface with the Medipac billing system that is programmed to *stop* the bill and send it to the Consolidated Business Office (CBO).
- The service will not interface with the Chartflo system (coding) so the coders will not see this activity and reports will not be generated