

Part VII: Plan Codes and Other Billing Issues

Table of Contents	Page
Research Plan Code	VII-2
How to Schedule a Service	VII-4
Instructions for Reviewing Bills for Research-Related Items and Services	VII-8
Billing Statements	VII-10
Outstanding Bills and Accounts Receivable	VII-12
Frequently Asked Questions About Research Site Detail Aging Report	VII-13
Research Participant Reporting	VII-15

Research Plan Code

Purpose

The purpose of this section is to define the Research Plan Code (RPC) and to explain its use as a component of Allina's Research Compliance Program. The RPC provides Allina with a mechanism to temporarily hold the patient claim allowing it to be sent to the research site for review. This allows any non-billable items or services to be removed before the claim is submitted to a third party payer. Research Compliance Policy RES 305.00 and its associated procedure RES 305.01 provide guidance on applying for a RPC and its use. Each research site will have its own RPC assigned by Allina SPA.

Scheduling a Service Using the Research Plan Code

The research site must determine if a research-related service is billable or non-billable prior to ordering the service. The following sources (refer to Part II) also provide assistance in determining if the item or service is billable or non-billable:

- National Coverage Decision (NCD) Algorithm
- Medicare Outpatient Self-Administered Drug Algorithm
- Clinical Trials for which No Reimbursement is Allowed Algorithm

When scheduling research items and services, refer to the criteria outlined in the NCD, as well as other materials presented in Part II, "Billing Guidance" of this Guide.

Billable is a generic term that refers to the proper and legal submission of a claim for reimbursement for the provision of an item or service to a third party, including private and government payers, for payment in accordance with that payer's policies.

Non-billable is the generic term for items or services that cannot be submitted for payment to a third party insurance payer.

Qualifying Trial is a trial that meets all the qualifying criteria outlined in the NCD. A copy of the NCD is in Part II, "Billing Guidance" of this Guide or at <http://cms.hhs.gov/coverage/8d.asp>.

Non-qualifying Trial is any trial that does not meet the qualifying criteria outlined in the NCD. There are three types of non-qualifying trials: "Medicare Outpatient Self-Administered Drug," "Clinical Trials for which No Reimbursement is Allowed," and "Other Covered Trials."

Medicare Outpatient Self-Administered Drug – a trial that does not meet the qualifying criteria of the Medicare Coverage of Clinical Trials ~ National Coverage Decision, but follows the standard of medically reasonable and necessary. Self-administered outpatient drugs would be an example. See Part II of this Guide for further information.

Clinical Trial for Which No Reimbursement is Allowed – a trial that does not meet the qualifying criteria of the Medicare Coverage of Clinical Trials ~ National Coverage Decision and is specifically excluded from coverage by Medicare (e.g., Category A medical devices). See Part II of this Guide for further information.

Other Covered Trials – a trial that does not meet the qualifying criteria of the Medicare Coverage of Clinical Trials ~ National Coverage Decision, but may be billed to a third party payer under other rules (e.g., Category B medical devices).

Research Service Form

Allina SPA created a Research Service Form (RSF) (see section VIII) to communicate to coding personnel that 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.

By submitting the RSF at the time the research services are rendered, the research site communicates to the coding department that 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

How to Schedule a Service

Outpatient Research-Related Items or Services

Qualifying Trials

Before scheduling, use the “NCD Algorithm” in Part II of this Guide for assistance in determining billable and non-billable items and services.

Billable Items and Services or Routine Care

These instructions are for instances in which only routine care or billable services are ordered.

The research site:

- contacts the service department to schedule the service;
- completes the RSF if applicable;
- writes its RPC box of the RSF form (*Note: This is a tracking mechanism and should not result in the RPC being added to the bill*);
- faxes the form to the service department; and
- follows Allina facility guidelines for proper ordering of services—a must.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Non-billable/Combined Billable and Non-billable/Unknown Items and Services

These instructions apply if any part of the items and/or services ordered are non-billable, or the billing status is unknown.

The research site:

- contacts the service department to schedule the service;
- informs scheduling staff that the service is for a research participant;
- provides scheduling staff with the RPC (Allina scheduling staff will place this RPC in a specific field in the scheduling system (either field 14 or field 22 depending on the system));
- completes the RSF if applicable;
- writes in the RPC;
- faxes the form to the service department; and
- follows Allina facility guidelines for proper ordering of services—a must.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Non-Qualifying Trials

There are three types of non-qualifying trials: Medicare Outpatient Self-Administered Drug Trials, Clinical Trials for which No Reimbursement is Allowed, and Other Covered Trials. Before scheduling, use the algorithms in Part II of this Guide for assistance in determining billable items and services.

Medicare Outpatient Self-Administered Drug Trials (refer to Part II)

Routine Care Items and Services

These instructions are for instances in which only routine care is ordered.

The research site:

- contacts the service department to schedule the service.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Items or Services that are Not Routine Care

These instructions apply if any part of the items and/or services ordered are non-billable or the billing status is unknown.

The research site:

- contacts the service department to schedule the service;
- informs the scheduling staff that the service is for a research participant;
- provides the scheduling staff with the RPC; and
- follows Allina facility guidelines for proper ordering of services—a must.

Allina scheduling staff will place this RPC in a specific field in the scheduling system (either field 14 or field 22 depending on the system). Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

No Reimbursement Allowed Trials (refer to Part II)

All items and services provided after study enrollment

The research site:

- contacts the service department to schedule the service;
- informs the scheduling staff that the service is for a research participant;
- provides the scheduling staff with the RPC; and
- follows Allina facility guidelines for proper ordering of services—a must.

Allina scheduling staff will place this RPC in a specific field in the scheduling system (either field 14 or field 22 depending on the system). Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Note: *Items and services provided to the patient prior to enrollment in the trial may be billable. See Part II for guidance.*

Other Covered Trials

Routine Care Items and Services

These instructions are for instances in which *only routine care* is ordered.

The research site:

- contacts the service department to schedule the service.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Items or Services that are Not Routine Care

These instructions apply if any part of the items and/or services ordered are non-billable or the billing status is unknown.

The research site:

- contacts the service department to schedule the service;
- informs the scheduling staff that the service is for a research participant; and
- provides the scheduling staff with the RPC.

Allina scheduling staff will place this RPC in a specific field in the scheduling system (either field 14 or field 22 depending on the system). Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Inpatient Research-related Items or Services

This section applies to patients who are known to be research participants at the point of scheduling or admission. For patients enrolled in studies *after* they are admitted, see “Patient Becomes a Research Participant after Entering an Allina Facility” section below.

Qualifying Trials

Use the “NCD Algorithm” in Part II of this Guide for assistance in determining billable items and services.

Billable Only Items and Services/Routine Care

The research site:

- follows standard procedures for ordering items and services;
- completes the RSF if applicable;
- writes NA in the RPC box of the RSF; and
- files the Research Service Form in the consent/authorization section of the patient’s chart.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Non-billable Only/Combined Billable and Non-billable/Unknown Items and Services

The research site:

- follows standard procedures for ordering items and services;
- provides scheduling and/or admitting with the RPC;
- completes the RSF if applicable;
- writes in the RPC; and
- files the RSF in the consent/authorization section of the patient’s chart.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Non-Qualifying Trials

Use the “Medicare Outpatient Self-Administered Drug Algorithm” (Part II) or the “No Reimbursement Allowed Algorithm” (Part II) for assistance in determining billable items and services.

Medicare Outpatient Self-Administered Drug Trials

Routine Care

The research site:

- follows standard procedures for ordering items and services.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Non-billable Only/Combined Billable and Non-billable/Unknown Items and Services

The research site:

- follows standard procedures for ordering items and services; and
- provides scheduling and/or admitting with the RPC.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

No Reimbursement Allowed Trials

All items or services

The research site:

- follows standard procedures for ordering items and services; and
- provides scheduling and/or admitting with the RPC.

Allina registration staff will obtain other payer/insurance information from the research participant so claims for billable services can be sent to a third party payer or other responsible party.

Note: *Items and services provided to the patient prior to enrollment in the trial may be billable. See Part II for guidance.*

Patient Becomes a Research Participant *After* Entering an Allina Facility

If a patient is placed in a trial after he or she has been admitted to an Allina facility, the research site must contact the registration department, inform them of this change, and provide them with the RPC. For example, if a patient enters the Emergency Department (ED), is hospitalized and placed in a trial by a research physician, the research site must immediately contact the registration department in order to place the RPC on the patient account.

The following are the individuals to contact in registration at the four metro hospitals.

Terry Koberstein	Rochelle Harris	Carol Williams	Pam Ketcham
Abbott Northwestern Hospital	Mercy Hospital	Unity Hospital	United Hospital
612-863-4385	763-236-7900	763-236-4568	651-241-5117

Instructions for Reviewing Bills for Research-Related Items and Services

Research Plan Code

If the research site uses its Research Plan Code (RPC), the bill is stopped from being sent to a third party payer and is sent to the research site at the address on file with Allina SPA.

After receiving the initial bill, the research site must do the following on the invoice:

- identify (circle) which items or services are non-billable;
- write “all routine care” or “no research services” on the first sheet and return it to the Allina Consolidated Billing Office (CBO) if there aren’t any non-billable items or services. (Please note: if the bill doesn’t belong to your research site please contact SPA at 612-262-4927. Do not write “no research services” if the bill doesn’t belong to your research site);
- write the price negotiated and the discount with the service department for each non-billable item or service;
- Total the discounts and enter the number in the designated area on the CBO cover letter; and,
- return it to the Allina CBO within 10 business days.

If the research site does not receive the participant bill within fourteen business days, call the Allina CBO.

Note: *Each research site must have a process in place to identify when it hasn’t received a bill.*

After receiving the bill from the research site, the Allina CBO will do the following:

- move the non-billable items and services from the participant account to the research site vendor account;
- apply the discount from the cover letter that accompanied the bill;
- generate a vendor account statement and send it to the research site; and
- remove the research plan code from the patient account billing any remaining items and services to the responsible party (e.g., a third party payer).

Upon receiving the vendor statement from the Allina CBO, the research site should promptly pay the bill. The vendor statement will display the participant name, date of service and the item or service.

Patient Payment

The billing process outlined throughout this Guide relies on patients being responsible for any balances remaining on their accounts. All applicable deductibles and coinsurance rules apply to these services. The research site needs to communicate this to the participant to prevent any miscommunication about his or her responsibilities for the account. The research site should provide the name of the research site person designated to be contacted by a participant regarding the bill.

Issues when using a Research Plan Code

The research site may receive bills for other health care professional consultants when the RPC is used. The research sites should work with potential health care professionals prior to beginning the project.

- If the items or services are billable, indicate on the bill, the services are routine care and return the bill to the billing organization.
- If the items or services are not billable to a third party payer, remit payment to the billing site.
Example: A non-billable CT Scan is required for the protocol and performed. If the scan is read by a radiologist, he or she may bill the research site for the read.
- If a bill is received for which the date of service is not associated with the clinical trial, write “not a research bill” on the statement and return it to Jan Weleski at Allina’s CBO for correction.
Example: On January 1, Participant A was registered using the RPC, the research service was provided and the research site received the bill. The same person returns on January 10 for a non-research related service and the research site receives the bill in error.

Miscellaneous Billing and Vendor Account Issues

1. The research site address on file with SPA will be the only address used when sending vendor account statements billing a site for items and services with the RPC. It is the responsibility of the research site to notify SPA of billing address changes.

2. Guidance for contacting Allina regarding vendor and patient accounts
SPA is responsible for:
 - answering questions and providing education around issues with respect to vendor accounts and using the RPC;
 - monitoring vendor accounts for payment;
 - handling requests for RPCs;
 - regulating the RPC process; and
 - troubleshooting issues with CBO.Consolidated Business Office (CBO) (612-775-9170) is responsible for:
 - moving charges from a patient account to a vendor account;
 - sending a participant bill to the research site when there are non-billable services;
 - sending the Vendor Account Statement;
 - assisting SPA in the monitoring of delinquent accounts;
 - assigning RPCs at the direction of SPA; and
 - applying payments to vendor and patient accounts (contact 612-775-9000).Service Departments are responsible for:
 - entering the correct charges on the patient/participant accounts (if research site is not charged appropriately, directly contact the department that provided the item or service).

3. Each site may be assigned two vendor accounts: a lab vendor account and a vendor account for all other charges, depending on the situation.

4. Research sites are responsible for the management of their RPC and vendor accounts. The research site should promptly notify the CBO (612-775-9170) if an error occurs on the vendor statement.

Billing Statements

Billing of research charges within Allina's billing system is often challenging. Sometimes this is due to the computer system (Medipac) used or the mechanisms in place to ensure that a bill is stopped. Scheduling a participant for a research service and ultimately having the charge removed is the most complex issue of the SPRP.

Participant Statement

Medipac generates the Participant Statement approximately three days after discharge or date of service. This statement groups the charges by department code to assist in identifying research charges. Due to the complexities of the system, it is only available once and cannot be recreated. If there are changes to the account that render the Participant Statement inaccurate, the CBO will send a screen print of the account. Examples of each type of statement can be found in the training materials.

Note: *The Participant Statement may not be generated for every account because of changes that may have been made to the account before the statement drops. If that is the case, you will be sent a screen print.*

Screen Print

The Screen Print prints one page of the account as it appears within Medipac. The Screen Print is printed when no Participant Statement is printed or another request for action is sent by the CBO.

UB-92 (Form 1450)

The UB-92 is the billing form used to bill inpatient hospital services to third party payers. Typically, this form is not sent to research sites unless an error occurred in the scheduling or registration process.

Form 1500

Form 1500 is used to bill professional services or outpatient services not in a hospital to third party payers. There are a couple of different ways you may receive a bill for professional fees. In addition to claims processed by Allina Professional Services (APS), SPA has designed an Access database to process these claims and send them to the research site for action. The address at the bottom of Form 1500 should say Allina Health System; likewise the bills created by SPA have our address in the top left corner. If Allina Health System or Sponsored Projects Administration do not appear, the bill belongs to a different entity. Below are the actions research sites should take to process the bills:

CMS-1500 Form

- If the bill is for a research service, payment must be sent with the claim to the address on the bottom of the 1500 form.
- The bill should be marked similarly to claims being sent to the Allina CBO; identify discounts and to which services the payment should be applied.

- If the bill is for routine care and should not be paid by the research site, indicate “not research” next to the charge on the bill and return it to: Sponsored Projects Administration, Allina Health System, Internal Zip 10105, Minneapolis, MN 55440-0043
- Research sites may be responsible for claims not returned in a timely manner.

SPA Statement

- Each listing within the statement is for a different time or date of service.
- The bill should be marked similarly to claims being sent to the Allina CBO; identify discounts and to which services the payment should be applied.
- Payment must be included with the statement.
- If the bill is for routine care and should not be paid by the research site, indicate “not research” next to the charge on the bill and return it to SPA.
- Research sites may be responsible for claims not returned in a timely manner.

Vendor Statements

As described previously, charges identified as non-billable to third party payers are transferred to vendor accounts. There are two types of vendor statements: Patient Statement of Account and Vendor Itemized Statement. Examples of each statement can be found in the training materials.

Patient Statement of Account

The Patient Statement of Account resembles an actual bill that is sent to patients, but the research site is the patient. It contains address information at the top and lists the name, date of service, service and either the gross charge or discount. Medipac automatically prints this statement once a month. Examples of this statement can be found in the training materials.

Note: *The Vendor and Patient Statements of Account are also used by the Allina Lab.*

Itemized Vendor Statement

The Itemized Vendor Statement is a special report created to group the charges with the discounts by the participant’s name. It resembles the Participant Statement discussed earlier. This report is sent by SPA approximately once a month. Examples of this statement can be found in the training materials.

Outstanding Bills and Accounts Receivable

It is the responsibility of every research site that uses the research plan code to promptly process all claims sent by Allina, whether it be screen prints, Participant Statements, Vendor Statements, etc. It is the research site's responsibility as long as the site's research plan code appears on the account. If Allina is unable to meet filing deadlines due to inaction by the research site, the site may be responsible for the entire bill.

Outstanding Bills

Outstanding bills are Participant Statements or Screen Prints sent by the Allina CBO that require research sites to identify which services are related to research. Allina expects the research sites to respond in a timely manner, which is considered less than 14 business days after receipt, or 21 business days after discharge or date of service. Because of the potential for research items and services being on a bill, Allina is unable to bill the responsible party (i.e., the patient or third party payer) until the research items and services have been removed. This has a significant financial impact on Allina and delays may result in sanctions on the research site.

If the research site believes that an error is on the bill, it needs to be brought to SPA's attention for action. SPA will work with the research site to resolve the issue. Simply returning the bill to the CBO may not result in a resolution.

Note: *Each research site should have a system in place to identify if it hasn't received a bill.*

Research Site Aging Report

SPA has created a report to assist itself and research sites in identifying accounts that are awaiting action or referred to as "on hold." A Frequently Asked Questions document discussing the Research Site Aging Report is provided on the next page.

Accounts Receivable

Each research site with a research plan code is provided a vendor account to accept non-billable charges. It is the research site's responsibility to promptly pay the charges listed on the account unless there is a disputed item, in which case it should be brought to SPA's attention.

Vendor accounts that are past due, may result in sanctions against the research site, including placing a halt to the project and no new projects being allowed in Allina facilities.

Frequently Asked Questions about the Research Site Detail Aging Report

Q1. What is a hold?

A1. In the context of research within Allina, it is a patient account that has not been billed to a third party because a research plan code is attached to it. Accounts may be held for various reasons, some under the direction of the research site and sometimes under the restriction of SPA in the case of a billing error.

Q2. What is the Hold Report?

A2. The Hold Report is a daily report printed from our hospital billing system showing accounts that are on hold because a research plan code is attached to them. The Hold Report is used by SPA for various reasons, such as tracking the days that an account is on hold, identifying which research plan codes are being used, and summarizing the total dollar amount of the accounts on hold. The most important issue is the total dollar amount on hold because of its impact to the accounts receivable. The Allina CBO also uses the report to send out bills to the research sites.

Q3. What is the Research Site Detail Aging Report (Aging Report)?

A3. The Aging Report is a tool created to inform research sites of accounts that appear on the Hold Report with their research plan code and to help SPA to follow-up on those outstanding accounts. It is important to note that it is a tool and it may contain incorrect information from the research site's perspective. However, it is information from our billing system and it is each research site's responsibility to inform SPA of any corrections.

SPA plans to send this report out at least once a month or more often if the balances of the Hold Report warrant.

Q4. The Aging Report shows 14 days on Hold and I just received the bill yesterday. Can you explain this?

A4. The Aging Report calculates days when it appears on a Hold Report and is recorded in the SPA database. The Hold Report lists the accounts on hold because the research plan code was used on the account. There are various reasons why this may have happened; such as, having an incorrect address, the bill may not have been printed, the CBO did not have time to run the bill, or mail delays.

We understand the system is not ideal but believe that there is enough flexibility in the system to accommodate delays.

Q5. I sent the bills back so why are they still showing up on the Aging Report?

A5. SPA gathers the information from the Hold Report every day and the Aging Report is accurate on the day it is sent. It can take time to remove accounts from hold after a research site returns them.

Q6. Why are accounts on hold longer than 21 days and large account balances a priority?

A6. Allina is trying to decrease accounts receivable (A/R) balances for better cash management. Because the accounts on hold for research are unique, these account balances are considered to be worse than typical A/R balances and garner increased scrutiny of senior management.

Q7. Will Allina cancel my project if the days on hold are more than 21 days?

A7. We do not plan to stop any projects within Allina that do not meet the 21-day deadline. However, Allina may end its participation if the research site consistently falls more than 45 days behind without good cause. In addition, any future projects seeking Allina services could be delayed or not approved.

SPA will first take steps to work with the research site to decrease the delays. If that proves unsuccessful, SPA will discuss the next steps with the Accountable Executive at the Allina facility.

Q8. What are some tips for limiting the accounts on hold?

A8:

- Review each bill *immediately* upon receipt for research charges—don't wait for several bills to arrive.
- Send payment only with the new CMS-1500 billings provided by SPA—send no payment with the CBO bills.
- Return the bills promptly so the CBO can transfer the charges to the vendor account.
If you think an item on the report is incorrect, please contact Carmi Anderson at 612-262-4927 or Kurt Sargent at 612-262-4926.

Research Participant Reporting

Purpose

Allina Sponsored Projects Administration requires that participant names that have services, be submitted on a monthly basis. This will assist in auditing and monitoring done by Allina. Please refer to RES 311.00 and RES 311.01 for additional information.

Scope

This applies to all research sites that have active research projects being conducted within Allina. Active research projects, as it applies to this procedure, are projects that have been submitted to SPA and are not closed. Please see Research Policy RES 311.00 for additional information.

Procedure

On a monthly basis, the research site will submit the following information for the research-related services performed during the previous month: (1) participant name, (2) date of service, (3) Allina facility where the services were performed and (4) study name. Non-research related services do not need to be reported.

Each month, SPA will send a reminder via e-mail to the account contact for the research site to submit the names of persons that received services during the previous month. A response is required. The notice will contain the deadline for submission, but will generally be ten days after the e-mail is distributed. Those research sites that do not respond or request an extension may have their projects suspended.

Note: The data may be sent using one of the following methods: (1) via e-mail, (2) mail or (3) fax. Any submissions using e-mail should use HIPAA compliant security measures.

Contact Carmi Anderson at 612-262-4927 or Kurt Sargent at 612-262-4926 if you have any questions about this procedure.