

Part II: Billing Guidance Information

Table of Contents	Page
Introduction	II-2
Medicare National Coverage Decision (NCD)	II-3
Medicare Coverage Policy ~ Clinical Trials National Coverage Decision	II-6
Intermediary and RHHI Provider Bulletin	II-10
Coverage of Clinical Trial Services Questions & Answers	II-14
Tools for Interpreting the National Coverage Decision (NCD)	II-19
Complications	II-26
Miscellaneous Billing Issues	II-27

Note:

The documents provided in the first part of the section are selected portions of the Medicare Clinical Trials ~ National Coverage Decision (NCD), Provider Bulletin, and Questions and Answers. The documents are provided for your convenience. Research sites are responsible for making sure they have the most current information. The information can be found on the Centers for Medicare and Medicaid Services (formally called Health Care Financing Administration (HCFA) Web site: <http://cms.hhs.gov/coverage/8d.asp>.

Introduction

This section of the Guide provides information about the Medicare Coverage of Clinical Trials ~ National Coverage Decision (NCD) and other guidance on billing third party payers for items and services related to a patient's participation in a clinical trial. The NCD, a national coverage policy issued September 2000, clarifies and extends coverage of the cost of certain (qualifying) clinical trials. The NCD identifies which trials are eligible for Medicare reimbursement and lists the types of items and services that may be reimbursed.

It is essential that the research site become familiar with the NCD before beginning the Setup Worksheets. In order to complete the Setup Worksheets correctly, the investigator must determine if the trial meets the qualifying criteria listed in the NCD, and must understand how the NCD affects reimbursement for research-related medical expenses. The research site is strongly encouraged to read the NCD and supporting CMS documents provided in the following pages. SPA has also provided algorithms and other documentation it developed to assist you in interpreting the NCD.

The National Coverage Decision
Medicare Coverage Policy ~ Clinical Trials
Final National Coverage Decision
September 19, 2000

This national coverage policy is based upon the authority found in §1862(a) (1) (E) of the Social Security Act (Act). It is binding on all Medicare carriers, fiscal intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, and Medicare+Choice organizations (§1852(a)(1)(A) of the Act). In addition, an administrative law judge may not disregard, set aside, or otherwise review a national coverage decision issued under §1862(a) (1) of the Act. 42 C.F.R. §405.860.

Clinical Trials

Effective for items and services furnished on or after September 19, 2000, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise 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 the control arms of a clinical trial except:

- the investigational item or service, itself;
- 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 CT 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.

Routine costs in clinical trials include:

- items or services that are typically provided absent a clinical trial (e.g., conventional care);
- 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 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.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies or the regulations on category B investigational device exemptions (IDE) found in 42 C.F.R. §405.201-405.215 and §411.15 and §411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare contractors' local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. (Refer to MCM 2300.1 and MIM 3101.) However, if the item or service is not covered by virtue of a national non-coverage policy in the Coverage Issues Manual and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

Requirements for Medicare Coverage of Routine Costs

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. 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;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Qualification Process for Clinical Trials

Using the authority found in §1142 of the Act (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (Panel) composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection, and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This Panel is not reviewing or approving individual trials. The multi-agency Panel will meet periodically to review and evaluate the program and recommend any necessary refinements to CMS.

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead Principal Investigator certifies that the trial meets the criteria. This process will require the Principal Investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency 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 for administrative purposes, once the registry is established.

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

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA.
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA.
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA.
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the 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.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified or have certified that they meet the qualifying criteria unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Should CMS find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §1879, §1842(l), or §1834(j)(4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's Principal Investigator may be pursued.

Medicare regulations require Medicare+Choice (M+C) organizations to follow CMS's national coverage decisions. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval. For the initial implementation, Medicare contractors will pay providers directly on a fee for service basis for covered clinical trial services for beneficiaries enrolled in M+C plans.

See notes at the start of Part II

Medicare Coverage Policy ~ Clinical Trials

Effective September 19, 2000

Provider Bulletin

(For more information, contact clinicaltrials@cms.hhs.gov.)

Some of the information
pertaining to coding has
changed.
Please refer to the Program
Memorandum
on page Part II-20.

CARRIER AND DMERC PROVIDER BULLETIN

"On June 7, 2000, the President of the United States issued an executive memorandum directing the Centers for Medicare and Medicaid Services (CMS) to "explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials." In keeping with the President's directive, this National Coverage Decision (NCD) serves to define the routine costs of clinical trials and identify the clinical trials for which payment for such routine costs should be made for eligible services furnished on or after September 19, 2000.

CMS has developed a National Coverage Determination (NCD) which can be accessed and downloaded from the CMS web page at <http://www.cms.hhs.gov/coverage/8d.asp>. This NCD states that Medicare covers: 1) the routine costs of qualifying clinical trials as well as 2) reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. This instruction addresses routine costs of qualifying clinical trials including complications resulting from qualifying clinical trials. All other Medicare rules apply.

Clinical Trial Services That Qualify for Coverage

Clinical trial services covered by Medicare must meet both the following requirements:

- 1. Qualifying Trial.** In order to be covered, the service must be part of a trial that meets all of the following criteria in order to be considered a qualifying trial:
 - a) Evaluates a Medicare Benefit.** The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
 - b) Has a Therapeutic Intent.** The trial must have a therapeutic intent (i.e., is not designed exclusively to test toxicity or disease pathophysiology).
 - c) Enrolls Diagnosed Beneficiaries.** Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
 - d) Has Desirable Characteristics.** The desirable characteristics are listed in the NCD.
 - **Deemed Trials.** Some trials are considered automatically deemed as having desirable characteristics. They include: (Effective September 19, 2000)
 - trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DOD), and Department of Veterans Affairs (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 Food and Drug Administration (FDA); and

- drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) are deemed until the 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.

Until the Medicare clinical trials registry is established, the sponsors of both IND trials and IND-exempt trials must identify themselves by e-mail to clinicaltrials@cms.hhs.gov for administration, payment and program integrity purposes.

- **Self-Certified Trials.** In the future, a multi-agency Federal panel (see NCD for further details) will develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics as stated in the NCD. ***No trials are covered based upon self-certification at this time.***

2. Routine Costs. Routine costs of a clinical trial include all items and services that are provided in either the experimental or the control arms of a trial except those listed below as not covered. Services provided to Medicare beneficiaries in both the experimental group and the control group are eligible for coverage provided that all other criteria in this instruction are met.

Routine costs do NOT include (and are therefore are not covered):

- the investigational item or service, itself;
- items and services:
 - for which there is no Medicare benefit category, or
 - which are statutorily excluded, or
 - that fall under a national noncoverage policy;
- items and services furnished solely to satisfy data collection and analysis needs that are 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 trial; and
- items and services provided solely to determine trial eligibility.

Routine costs DO include (and are therefore covered):

- items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care);
- items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent),
- items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

This national coverage policy is based upon the authority found in §1862(a)(1)(E) of the Social Security Act (Act). It is binding on all Medicare carriers, fiscal intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, and Medicare+Choice organizations (§1852 (a)(1)(A) of the Act)."

Effective for dates of service *on or after* September 19, 2000 when submitting claims for services or items that meet the requirements as outlined in the final National Coverage Decision, you must identify these services with the "QV" procedure code modifier. "QV" - "Item or service provided as routine care in an approved clinical trial" (The full coverage policy regarding clinical trials may be accessed at <http://www.cms.hhs.gov/coverage/8d.asp>).

The modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV modifier. Finally, items and services customarily provided by the research sponsor free of charge for any enrollee in the trial may not be billed.

In addition to the QV modifier, providers must also report diagnosis code V70.5 (Health Examination of Defined Subpopulations) as a secondary diagnosis for patients participating in Medicare covered clinical trials.

The QV modifier and V70.5 diagnosis code will serve as your attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

Submit separate line items for clinical trial services when billing other covered services not directly related to a Medicare qualifying clinical trial on the same claim.

When submitting claims with the QV procedure code modifier and V70.5 diagnosis code, the billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information should not be submitted with the claim but must be provided if requested for medical review. A copy of the signed informed consent document must also be made readily available if requested for medical review activities.

Payment for these qualifying clinical trial services furnished on or after September 19, 2000, will be paid based on the payment methodology applicable for the service that was furnished (e.g., Physician Fee Schedule, Lab Fee Schedule, DME Fee Schedule, Reasonable Charge, etc.). All applicable deductible and coinsurance rules apply to these services.

- If you have a claim for a Medicare qualifying clinical trial service that has been denied for a date of service on or after September 19, 2000, the action you take to get the claim paid will depend on whether the service was initially submitted with the QV modifier and ICD-9 code.
- Initial Claim did not include the QV Modifier and ICD-9 code V70.5 – If clinical trial routine care services on a claim are denied and were not identified as clinical trial services (i.e., the clinical trial modifier and ICD-9 code was not included), resubmit the services on a new claim with the QV modifier and ICD-9 code V70.5 for the care or medical complications arising from a Medicare qualifying clinical trial.
- Denied Service included the QV Modifier and ICD-9 code – If a service Medicare covers is billed with the QV modifier and ICD-9 code and initially denied (e.g., for medical necessity or utilization) contact us (insert the phone number for providers) [sic] and request an adjustment to the claim. If appropriate, we will adjust and pay the claim."

Payment of Clinical Trial Services for Managed Care Enrollees

Payment for clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans will be made on a fee for service basis by the Medicare contractors that process fee for service claims. Providers will need to submit fee for service bills for Medicare covered clinical trial services furnished to managed care enrollees. The payment amounts will be based on the applicable Medicare fee schedules for such services.

INTERMEDIARY AND RHHI PROVIDER BULLETIN

On June 7, 2000, the President of the United States issued an executive memorandum directing the Centers for Medicare and Medicaid Services (CMS) to “explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials.” In keeping with the President's directive, this National Coverage Decision (NCD) serves to define the routine costs of clinical trials and identify the clinical trials for which payment for such routine costs should be made for eligible services furnished on or after September 19, 2000.

CMS has developed a National Coverage Determination (NCD) which can be accessed and downloaded from the CMS web page at <http://www.cms.hhs.gov/coverage/8d.asp>. This NCD states that Medicare covers: 1) the routine costs of qualifying clinical trials as well as 2) reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. This instruction addresses routine costs of qualifying clinical trials including complications resulting from qualifying clinical trials. All other Medicare rules apply.

Clinical Trial Services That Qualify for Coverage

Clinical trial services covered by Medicare must meet both the following requirements:

1. Qualifying Trial. In order to be covered, the service must be part of a trial that meets all of the following criteria in order to be considered a qualifying trial:

- a) Evaluates a Medicare Benefit.** The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- b) Has a Therapeutic Intent.** The trial must have a therapeutic intent (i.e., is not designed exclusively to test toxicity or disease pathophysiology).
- c) Enrolls Diagnosed Beneficiaries.** Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
- d) Has Desirable Characteristics.** The desirable characteristics are listed in the NCD.

Deemed Trials. Some trials are considered automatically deemed as having desirable characteristics. They include: (Effective September 19, 2000)

- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DOD), and Department of Veterans Affairs (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 Food and Drug Administration (FDA).

Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) are deemed until the 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.

Until the Medicare clinical trials registry is established, the sponsors of both IND trials and IND-exempt trials must identify themselves by e-mail to clinicaltrials@cms.hhs.gov for administration, payment and program integrity purposes.

Self-Certified Trials. In the future, a multi-agency Federal panel (see NCD for further details) will develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics as stated in the NCD. ***No trials are covered based upon self-certification at this time.***

2. Routine Costs. Routine costs of a clinical trial include all items and services that are provided in either the experimental or the control arms of a trial except those listed below as not covered. Services provided to Medicare beneficiaries in both the experimental group and the control group are eligible for coverage provided that all other criteria in this instruction are met.

Routine costs do NOT include (and therefore are not covered):

- the investigational item or service, itself;
- items and services:
 - for which there is no Medicare benefit category, or
 - which are statutorily excluded, or
 - that fall under a national non-coverage policy;
- items and services furnished solely to satisfy data collection and analysis needs that are 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 trial; and
- items and services provided solely to determine trial eligibility.

Routine costs DO include (and therefore covered):

- items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care);
- items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent),
- items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

This national coverage policy is based upon the authority found in §1862(a)(1)(E) of the Social Security Act (Act). It is binding on all Medicare carriers, fiscal intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, and Medicare+Choice organizations (§1852 (a)(1)(A) of the Act)."

For claims with dates of service on or after September 19, 2000, submit claims for services that meet the requirements as outlined in the final National Coverage Decision for Medicare qualifying clinical trial services by reporting the ICD-9-CM diagnosis code of V70.5 (Health Examination of Defined Subpopulations). Report this code as the third or subsequent diagnosis code not as the principal diagnosis code on the claim. Continue to code the principal diagnosis code chiefly responsible for the service.

The ICD-9 code is used to identify services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered clinical trial. Services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered. In addition, services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using this ICD-9 code. Finally, items and services customarily provided by the research sponsors free of charge for any enrollee in the trial may not be billed.

This code will serve as your attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

When submitting claims with the V70.5 diagnosis code you must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information should not be submitted with the claim but must be provided if requested for medical review. A copy of the signed informed consent document must also be made readily available if requested for medical review activities.

Submit separate line items for clinical trial services when the claim includes other covered services not directly related to a Medicare qualifying clinical trial.

Payment Requirements

Payment for these Medicare qualifying clinical trial services furnished on or after September 19, 2000, will be paid under current payment methodologies specific to your provider type and the service being provided. All applicable deductible and coinsurance rules apply to clinical trial services with one exception. In the case of fee for service claims for managed care enrollees, the beneficiary will not be responsible for the Part A deductible.

Where the payment is bundled (e.g., DRG payments), Medicare will later adjust amounts paid for non-covered investigational items and services for which payment should not have been included as part of the bundled payment.

Billing Requirements

Bill on HCFA Form HCFA-1450 or electronic equivalent.

Applicable Bill Types--All institutional provider bill types (inpatient and outpatient) are applicable.

When utilizing the UB-92 flat file, use record type 40 to report bill type. Record type (Field No. 1), sequence number (Field No. 2), patient control number (Field No. 3), and type of bill (Field No. 4) are required.

When utilizing the hard copy UB-92 (Form HCFA-1450), report the applicable bill type in Form Locator (FL) 4 "Type of Bill."

When utilizing the Medicare A 837 Health Care Claim version 3051 implementations 3A.01 and 1A.C1, report the applicable bill type in 2-130-CLM01, CLM05-01, and CLM05-03.

ICD-9-CM Reporting--For claims with dates of service on or after September 19, 2000, report ICD-9 diagnosis code V70.5 (Health Examination of Defined Subpopulation) as the third or subsequent diagnosis code (not as the Principal Diagnosis) when billing for a Medicare qualifying clinical trial service.

When utilizing the UB-92 flat file, use record type 70, Other Diagnoses Code (Field No. 6-12) to report the ICD-9 code.

When utilizing the hard copy UB-92, report the ICD-9 code in Form Locators (FLs) 69-75 (Other Diagnoses Codes).

When utilizing the Medicare A 837 Health Care Claim version 3051 implementations 3A.01 and 1A.C1, report the ICD-9 in 2-225.A-HI04-02 through HI10-02.

When utilizing the Health Care Claim: Institutional 837 version 4010, report the ICD-9 in OTHER DIAGNOSIS INFORMATION HI02.

If a claim for a Medicare covered clinical trial service was erroneously denied for a date of service on or after September 19, 2000 [sic]. The action you take to receive payment for this service depends on whether the claim was initially submitted with the clinical trial diagnosis code.

Initial Claim Did Not Include the Clinical Trial Diagnosis Code –

Submit an adjustment bill with the clinical trial ICD-9 diagnosis code. If the claim or any line item on the claim is denied, notify us (insert the telephone number for providers) that the denied service(s) on the claim was related to a Medicare covered clinical trial and, if appropriate, payment will be made.

Inadvertently Denied Claim Was Submitted With the Clinical Trial Diagnosis Code (As the Third or Subsequent Diagnosis) –

Notify us [CMS] that a denied service(s) on the claim was related to a Medicare covered clinical trial service and, if appropriate, payment will be made.

Payment of Clinical Trial Services for Managed Care Enrollees

Payment for clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans will be made by the Medicare contractors that process fee for service claims. You will need to submit fee for service bills to those entities for covered clinical trial services furnished to Medicare managed care enrollees. Payment will be based on the current payment methodologies specific to your provider type and the service being provided. In addition, the Part A deductible is assumed to be met when billed on a fee for service basis for Medicare covered clinical trial services furnished to managed care enrollees.

Coverage of Clinical Trial Services Questions & Answers

Q1: What is the National Coverage Determination (NCD) regarding Medicare coverage of clinical trials?

A1: The NCD states that Medicare covers: 1) the routine costs of qualifying clinical trials as well as 2) reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

Q2: What is a qualifying clinical trial?

A2: A qualifying clinical trial must meet all of the following criteria.

Evaluates a Medicare Benefit: The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category.

Has a Therapeutic Intent: The trial must have a therapeutic intent (i.e., is not designed exclusively to test toxicity or disease pathology).

Enrolls Diagnosed Beneficiaries: Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

Has Desirable Characteristics: The desirable characteristics are listed in the NCD and are as follows:

1. the purpose tests interventions to potentially improve the participants' health outcomes;
2. 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;
3. the trial does not unjustifiably duplicate existing studies;
4. the trial design is appropriate to answer the research question being asked in the trial;
5. the trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. the trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. all aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Q3: Are there any trials that are considered to have desirable characteristics?

A3: Some trials are considered automatically deemed as having desirable characteristics. They include (effective September 19, 2000):

1. Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DOD), and Department of Veterans Affairs (VA).
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA.
3. Trials conducted under an investigational new drug application (IND) sponsored by the Food and Drug Administration (FDA).
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1). Unlike other deemed trials, the principal investigators of these trials must certify that the trials meet the qualifying criteria, once the criteria are established. If the trial does not meet the qualifying criteria or does not go through the certification process, the trials will lose Medicare coverage of routine cost

Q4: Can other clinical trials, not listed as a deemed trial, qualify for Medicare reimbursement?

A4: In the future, a multi-agency Federal panel (see NCD for further details) will develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics as stated in the NCD. These clinical trials are called Self-Certified Trials. **No trials are covered based upon self-certification at this time.**

Q5: What are considered to be routine costs of a clinical trial?

A5: They include all items and services that are provided in either the experimental or the control arms of a trial except those specifically stated as not covered. Services provided to Medicare beneficiaries in both the experimental group and the control group are eligible for coverage provided that all other criteria in this instruction are met.

Routine costs DO include (and therefore covered):

- Items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care).
- Items and services required for the provision of the investigational item or service (e.g.; administration of a non-covered chemotherapeutic agent).
- Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.
- Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

Q6: Are there specific services not covered as a routine cost?

A6: Yes, routine costs do NOT include (and therefore not covered):

- The investigational item or service, itself.
- Items and services:
 - for which there is no Medicare benefit category, or
 - which are statutorily excluded, or
 - that fall under a national non-coverage policy.
- Items and services furnished solely to satisfy data collection and analysis needs that are 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 trial.
- Items and services provided solely to determine trial eligibility.

Q7: What is the effective date for Medicare coverage of clinical trials?

A7: Clinical trial claims submitted for dates of service on or after September 19, 2000 are covered (providing that the clinical trial and services meet the requirements listed in the NCD).

Q8: Do deductibles and coinsurance apply to clinical trials?

A8: Applicable deductibles and coinsurance rules apply to clinical trial items and services for beneficiaries enrolled in Medicare fee-for-service. If the enrollee is a member of a Managed Care Medicare plan, any applicable deductibles are deemed met but fee-for-service coinsurance rules apply.

Q9: Is there a special billing form for clinical trial services?

A9: No. You should continue to use the forms they are currently using (either HCFA-1500 or HCFA-1450/UB-92 or the electronic equivalent).

Q10: Is there any specific documentation that is required in the medical record of a beneficiary that is participating in a clinical trial?

A10: You must include the following information in the beneficiary's medical record: trial name, sponsor, and sponsor-assigned protocol number. This information should not be submitted with the claim but must be provided if requested for post-payment review.

Q11: Should a copy of the consent form accompany the bill?

A11: No. A copy of the signed informed consent document must also be made readily available if requested for medical review activities.

Q12: How should the principal diagnosis be coded?

A12: The principle diagnosis should be coded according to ICD-9-CM coding guidelines.

Q13: How should clinical trial and non-clinical trial services be reported on the same claim?

A13: Clinical trial and non-clinical trial services should be reported as separate line items (i.e., they may not be co-mingled) when billing them on the same claim.

Q14: Who bears the risk for payment made on misidentified deemed trials?

A14: The party to whom we make payment is at risk for full recovery of payment made including interest required by law. We suggest that providers take steps before submitting claims to assure that a clinical trial is in fact deemed. The provider should be familiar with the types of trials listed as deemed in the NCD and PM, and contact the sponsor to obtain evidence that the trial is among these types. We also recommend that this evidence be maintained in the patient record.

Providers Using CMS-1500 Form

Q15: Are there any special billing requirements that apply to covered clinical trial services billed via the CMS-1500 or electronic equivalent?

A15: A new procedure code modifier "QV" is used to identify clinical trial services. The QV modifier is defined as, "Item or service provided as routine care in a Medicare covered clinical trial." In addition, this procedure code modifier must be accompanied by a secondary diagnosis code of V70.5, "Health Examination of Defined Subpopulations" on the claim.

Q16: Does the clinical trial procedure code modifier need to be listed only once on the HCFA-1500?

A16: The procedure code modifier "QV" is line-item specific.

Q17: How is the Medicare payment calculated for providers who bill using the HCFA-1500?

A17: The Medicare payment is based on the payment methodology applicable for the service that was furnished (e.g.; Physician Fee Schedule, Lab Fee Schedule, DME Fee Schedule, Reasonable Charge, etc.)

Q18: Do services that required a Certificate of Medical Necessity (CMN) for processing my HCFA-1500 still require a CMN?

A18: Yes. CMNs are still required for services that previously required a CMN.

Q19: What should providers who bill via the HCFA-1500 do if a Medicare qualifying clinical trial service is inadvertently denied?

A19: If a Medicare qualifying clinical trial service is denied for a date of service on or after September 19, 2000, the action you should take will depend on whether the denied service was initially submitted with the QV modifier and V70.5 ICD-9 code.

When clinical trial services are denied and were not coded as routine care clinical trial services on the claim (i.e., the clinical trial modifier and ICD-9 code was not included), you must resubmit the services on a new claim with the QV modifier and ICD-9 code for the routine care including medical complications arising from a Medicare qualifying clinical trial.

When a clinical trial service Medicare covers was billed with the QV modifier and ICD-9 code V70.5, but inadvertently denied (e.g., for medical necessity), you should contact the carrier and request that the claim be adjusted for payment of Medicare qualifying clinical trial services.

Providers Using the HCFA-1450 (UB-92) Form

Q20: How should clinical trial claims be coded on the HCFA-1450 (UB-92)?

A20: Clinical trial claims should be coded by reporting the ICD-9-CM diagnosis code of V70.5 "Health Examination of Defined Subpopulations." Report this code as the third or subsequent diagnosis code on the claim. Do not report V70.5 as the principal diagnosis code. V70.5 is used to identify services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare qualifying clinical trial.

Q21: How is payment calculated for providers billing on the HCFA-1450 (UB-92)?

A21: Covered clinical trial services are paid by intermediaries under current payment methodologies specific to the service(s) you provide and for claims with dates of service on or after September 19, 2000.

Q22: Are there specific bill types that apply?

A22: All bill types (inpatient and outpatient) are applicable.

Q23: What ICD-9 code is to be used when reporting a routine care clinical trial service on the HCFA-1450 (UB-92)?

A23: For claims with dates of service on or after September 19, 2000, you report ICD-9 diagnosis code V70.5 (Health Examination of Defined Subpopulations) as the third or subsequent diagnosis code (not as the principal diagnosis) when reporting a routine case clinical trial service.

Q24: What should providers who bill on the HCFA-1450 (UB-92) do if a qualifying clinical trial service is denied?

A24: When a Medicare qualifying clinical trial service is denied for a date of service on or after September 19, 2000, the action you should take depends on whether the claim was initially submitted with the clinical trial diagnosis code V70.5.

When a claim or a line item on the claim is denied and the service was for a routine clinical trial service but the V70.5 diagnosis code was not present on the claim (as the third or subsequent diagnosis), you must submit an adjustment bill including the ICD-9 clinical trial diagnosis code.

If a clinical trial service claim or trial specific item on the claim was inadvertently denied and the claim included the ICD-9 diagnosis code V70.5, you should contact the intermediary to request that it adjust the claim to pay for Medicare covered routine clinical trial services.

Denials for Claims Filed on the HCFA-1500

Q25: How should you use the HCFA-1500 to handle claims that have been inadvertently denied?

A25: When it is brought your attention that a Medicare qualifying clinical trial service was denied for a date of service on or after September 19, 2000, the action you take to adjust the claim depends on whether the claim was initially submitted with the clinical trial diagnosis code V70.5.

Q26: How should you use the HCFA-1500 to handle denied services that were not billed with the QV Modifier and ICD-9 code V70.5?

A26: When services on an initial claim are denied and were not coded as routine care clinical trial services (i.e., the clinical trial modifier and ICD-9 code was not included), you should contact your intermediary to request a claim adjustment to pay for Medicare covered routine clinical trial services.

Q27: How should you use the HCFA-1500 to handle inadvertently denied Services that were billed with the QV Modifier and ICD-9 code V70.5?

A27: Under certain circumstances, a service Medicare covers that is billed with the QV modifier and ICD-9 code V70.5 may be inadvertently denied (e.g., for medical necessity or utilization). In these situations, the provider should call the contractor and state that, as indicated on the claim, the service was part of a clinical trial and should not have been denied. Once brought to its attention, the contractor shall adjust the claim and approve Medicare covered services for payment.

Denials for Claims Filed on the HCFA-1450 (UB-92)

Q28: How should you use the HCFA-1450 (UB-92) to handle claims that have been inadvertently denied?

A28: When it is brought to your attention that a Medicare qualifying clinical trial service was denied for a date of service on or after September 19, 2000, the action you take depends on whether the claim was initially submitted with the clinical trial diagnosis code V70.5.

Q29: How should you use the HCFA-1450 (UB-92) to handle initial claims that did not include the clinical trial diagnosis code?

A29: When a claim or a line item on the claim is denied and the service was for a routine clinical trial service, you should contact your intermediary to request a claim adjustment to pay for Medicare covered routine clinical trial services.

Q30: How should you use the HCFA-1450 (UB-92) to handle inadvertently denied claims that were submitted with the clinical trial Diagnosis code (as the third or subsequent diagnosis)?

A30: If a claim or any item on the claim is inadvertently denied and the claim reflects the ICD-9 diagnosis code, you should contact your intermediary to request a claim adjustment to pay for Medicare covered routine clinical trial services.

Tools for Interpreting the Medicare National Coverage Decision (NCD)

What Tools Should I Use?

Using the description or diagram below determine which algorithm best fits with the type of project you are submitting information.

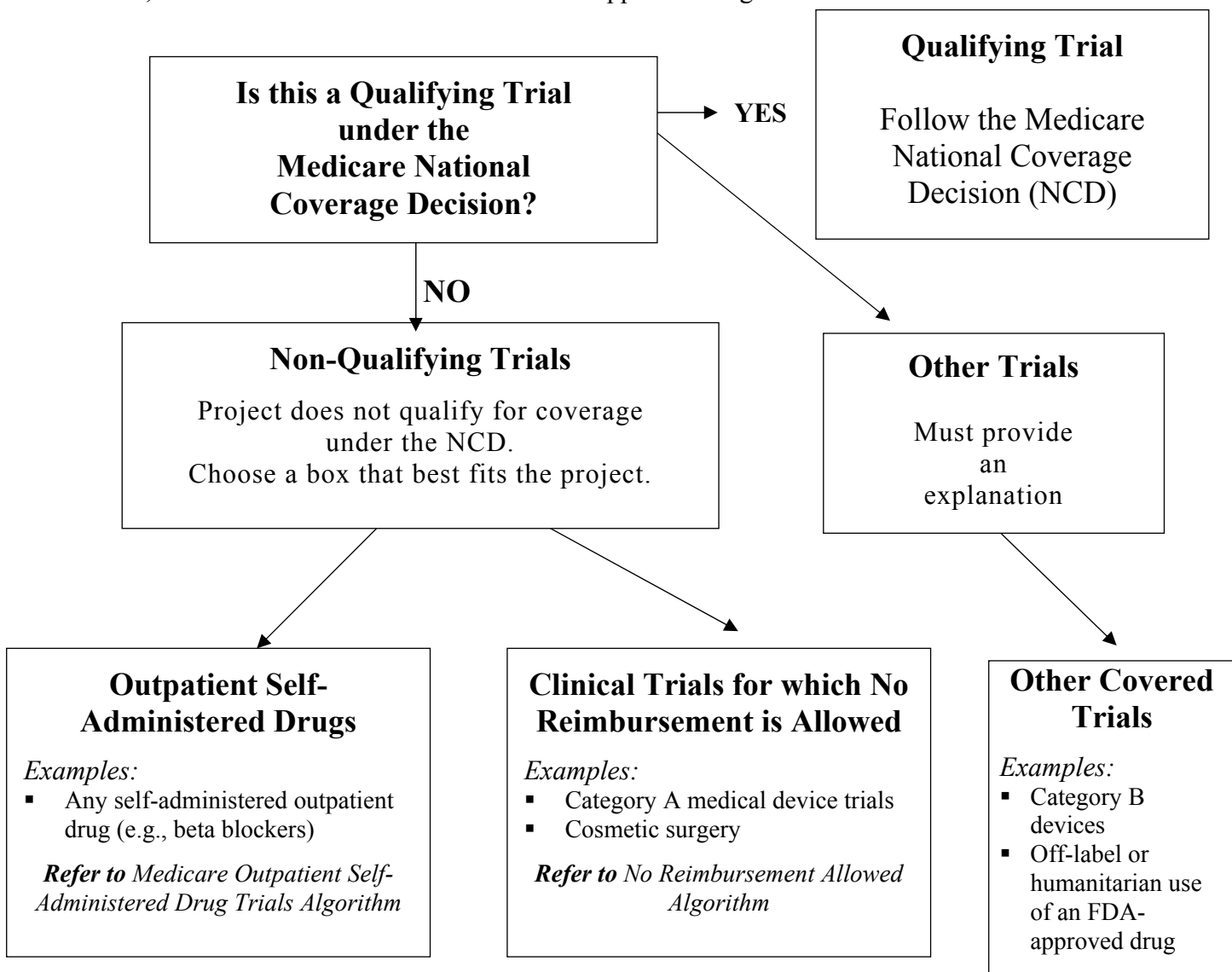
Qualifying Trials are trials that meet all the qualifying criteria outlined in the NCD. A copy of the NCD is in Part II, Billing Guidance, of this Guide or <http://www.cms.hhs.gov/>.

Non-Qualifying Trials are trials that do not meet the qualifying criteria outlined in the NCD. There are two types of non-qualifying trials: “Medicare Outpatient Self-Administered Drug Trials” and “Clinical Trials for which No Reimbursement is Allowed.”

Medicare Outpatient Self-Administered Drug Trials are trials that do not meet the qualifying criteria of the Medicare Coverage of Clinical Trials ~ National Coverage Decision, but follow the standard of medically reasonable and necessary.

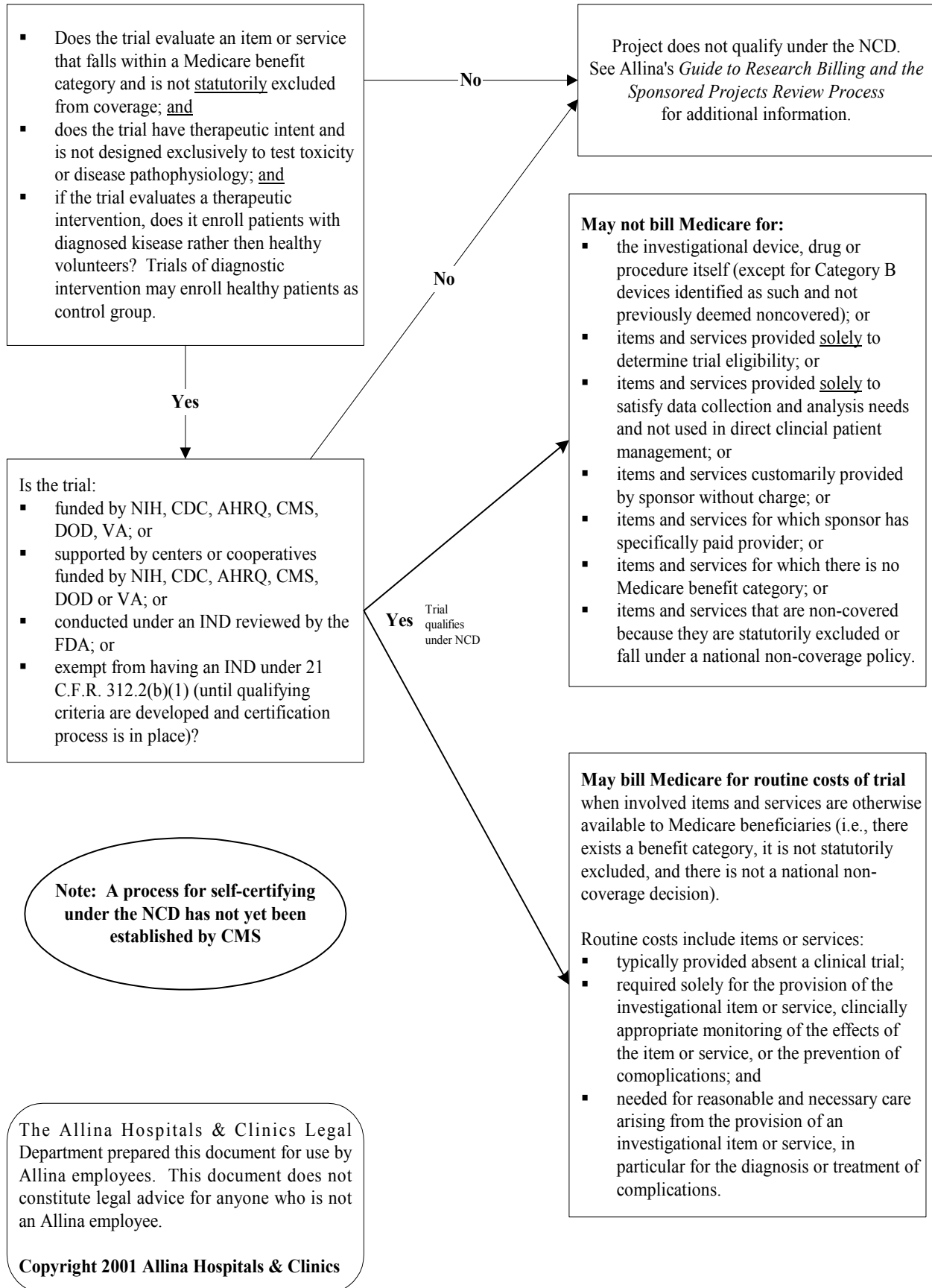
Clinical Trials for which No Reimbursement is Allowed are trials that do not meet the qualifying criteria of the Medicare Coverage of Clinical Trials ~ National Coverage Decision and are specifically excluded from coverage by Medicare (e.g., Category A medical devices).

Other Trials are trials that do not fit into the two aforementioned categories. Examples include: Category B devices, off-label or humanitarian use of a FDA-approved drug.



Medicare National Coverage Decision Clinical Trials Algorithm

(This algorithm must be used in conjunction with the narrative information in the Medicare National Coverage Decision. It is not intended to stand alone.)



Outpatient Self-Administered Drug Trials Exclusion

As outlined in the Medicare Coverage of Clinical Trials ~ National Coverage Decision (NCD), outpatient self-administered drug trials are excluded from coverage by third party payers that do not have an outpatient drug benefit available to its members or beneficiaries (e.g., Medicare). Third party payers that have a drug benefit may be billed using the NCD criteria. Allina Hospitals & Clinics Sponsored Projects Administration, in cooperation with legal counsel, has created the Outpatient Self-Administered Drug Trial Algorithm for those trials. This algorithm must be used to determine billable and non-billable items and services when the patient does not have an outpatient self-administered drug benefit category. The algorithm is on the next page of this Guide.

Medicare Regulations Pertaining to the Outpatient Drug Exclusion

NCD

Item one of the “Requirement for Medicare Coverage of Routine Costs” section in the NCD states, “The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).”

Medicare Regulations

Medicare Carriers Manual (MCM) §2049.5 Self-Administered Drugs and Biologicals--Drugs that are self-administered are not covered by Medicare Part B unless the statute provides for such coverage. This includes blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, certain oral anti-cancer drugs, and oral anti-nausea drugs when used in certain situations.

MCM §2049.2 Determining Self-Administration of Drug or Biological--Whether a drug or biological is of a type which cannot be self-administered is based on the usual method of administration of the form of that drug or biological as furnished by the physician. Thus, where a physician gives a patient pills or other oral medication, these are excluded from coverage since the form of the drug given to the patient is usually self-administered. Similarly, if a physician gives a patient an injection which is usually self-injected (e.g., insulin or calcitonin), this drug is excluded from coverage, unless administered to the patient in an emergency situation (e.g., diabetic coma). Where, however, a physician injects a drug which is not usually self-injected, this drug is not subject to the self-administrable drug exclusion (regardless of whether the drug may also be available in oral form) since it is not self-administrable in the form in which it was furnished to the patient. Whole blood is a biological that cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied. (See §2455 on Part B blood deductible.)

Example:

A person enrolled in Medicare is not feeling well and goes to see his/her physician. The physician, after conducting a physical exam, determines that the patient suffers from high blood pressure and enrolls the patient in an investigational outpatient self-administered drug trial that is being evaluated for the treatment of high blood pressure. The FDA does not approve the drug.

Analysis:

Initial visit: The initial visit is covered by Medicare because it was for a medically necessary and reasonable service. However, the medication is not covered because Medicare does not pay for any self-administered drugs, FDA approved or not.

Subsequent visits: On subsequent visits that are routine care the patient would receive if he/she were on an approved treatment drug are billable as routine care. The drug itself would never be covered unless it met the exception criteria outlined in Medicare Carriers Manual (MCM) §2049.5 or is excluded by other laws or regulations. Visits that are not routine care under standard treatment are not billable.

Medicare Outpatient Self-Administered Drug Trials Algorithm

(This algorithm must be used in conjunction with the narrative information found in Part II, Billing guidance, of this Guide. It is not intended to stand alone.)

The Medicare Coverage of Clinical Trials ~ National Coverage Decision (NCD), effective September 2000, requires that "the subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category...." For example, Medicare Carrier Manual Part III, 2049 explicitly excludes self-administered outpatient drugs as a benefit category from Medicare. Therefore, clinical trials of outpatient self-administered drugs are excluded from Medicare coverage under the NCD, unless the drugs are of the type that is subject to an exception to the general Medicare rule of non-coverage (e.g., certain chemotherapy drugs), or the applicable non-Medicare third party payer has an outpatient drug benefit (in which case, services related to an outpatient drug trial would presumably be covered if that third party payer follows the NCD). The algorithm appearing below should be used to analyze how items and services should be billed to Medicare or other payers that follow Medicare billing guidelines for outpatient self-administered drug trials. Part II of the Guide provides further instructions on the topic. **Note:** All other third party payer policies and rules apply. For example, if a patient needs to be pre-authorized for continued treatment under his/her managed care plan rules, that pre-authorization would still be required.

Initial Visit

The patient visit is for a medically necessary service as defined by Medicare or other third party payer (e.g., patient presents with chest pain and receives experimental drug)

May bill third party for:

- Routine care (care the participant would receive absent a clinical trial)

May not bill third party for:

- Investigational drug itself
- Time and effort (E/M) related to study enrollment
- Items or services that fall under a non-coverage policy
- Items or services that are statutorily excluded from Medicare coverage
- Items or services related to data collection, which are not needed in the direct and routine care of the patient
- Items or services used to determine trial eligibility, if that item or service was not called for in routine care
- Items or services provided free from the sponsor

Subsequent Visits

Follow-up Care

May bill third party for:

- Routine care (care the participant would receive absent a clinical trial)
- Drugs that are reimbursable by Medicare under exceptions to the general rules (e.g., certain oral anti-cancer drugs)

May not bill third party for:

- The investigational drug itself (unless a relevant exception to the general rule applies)
- Items or services provided to monitor the expected side effects of the drug to the extent that monitoring is not part of routine care)
- Items or services that fall under a non-coverage policy
- Items or services that are statutorily excluded from coverage (e.g., in connection with Medicare patients, another outpatient drug, or preventive care)
- Items and services related to data collection, which are not needed in the direct and routine care of the patient
- Items and services reimbursed to Allina or the physician as part of a global or specific fee for the services provided in the clinical trial paid either by a research sponsor or any payer

Complications

May bill third party for:

- Items or services ordinarily covered by the payer absent the clinical trial
- Items or services that are not part of a global fee for all the services provided in the clinical trial, either by a research sponsor or by another payer
- Items or services provided for unexpected complications (complications not contemplated in the study protocol)

May not bill third party for:

- Items or services provided for expected complications identified in the study protocol as a likely or possible result of the research-related intervention

Clinical Trials for which No Reimbursement is Allowed

Clinical Trials for which No Reimbursement is Allowed (referred to as “No-Reimbursement-Allowed”) are trials where the items and services are not billable after the initial visit or after enrollment in trial, provided the patient was seeking medically reasonable and necessary services. However, by statute or regulation the remaining items and services are not considered reasonable and necessary or are not covered (e.g., Category A device). When categories of services, items or devices are categorically excluded from coverage, the No Reimbursement Allowed Algorithm should be used and consulted.

42 CFR Sec. 405.207 **Services related to a non-covered device.** (a) when payment is not made. Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not “reasonable and necessary” under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a non-covered device, services furnished contemporaneously with and necessary to the use of a non-covered device, and services furnished as necessary after care that are incident to recovery from the use of the device or from receiving related non-covered services; (b) when payment is made. Medicare payment may be made for services, ordinarily covered by Medicare, to treat a condition or complication that arises because of the use of a non-covered device or from the furnishing of related non-covered services.

Example #1:

A person suffering chest pain visits a cardiologist for a medically reasonable and necessary visit. After performing the appropriate physical exam and diagnostic tests, the cardiologist determines that the patient needs a pacemaker. The physician recommends a new pacemaker being tested as part of a clinical trial. The pacemaker under consideration is a Category A device according to the Food and Drug Administration (FDA) guidelines. The patient undergoes the informed consent process and is placed on the clinical trial. Two days later, the patient enters an Allina Day Surgery facility to have the pacemaker implanted and is discharged the same day.

Analysis:

Initial visit: The examination and diagnostic tests for chest pain would be considered medically reasonable and necessary and the initial (first) visit should be covered and billable. However, no upward adjustment should be made for the additional time spent enrolling the patient in the trial.

Subsequent Visit: The patient comes to the Allina Day Surgery facility for implantation of the Category A device. None of the services related to the implantation of the device are billable, nor is any of the subsequent care because it does not meet the “medically reasonable and necessary” standard. Unexpected complications are covered.

Example #2:

A person visits a plastic surgeon to have a consultation about cheek implants for cosmetic purposes. Surgery for purely cosmetic purposes is not considered medically reasonable and necessary. The surgeon is participating in a trial testing a new cheek implant device. After the consultation, the patient is placed on study and the surgery is done within two weeks.

Analysis:

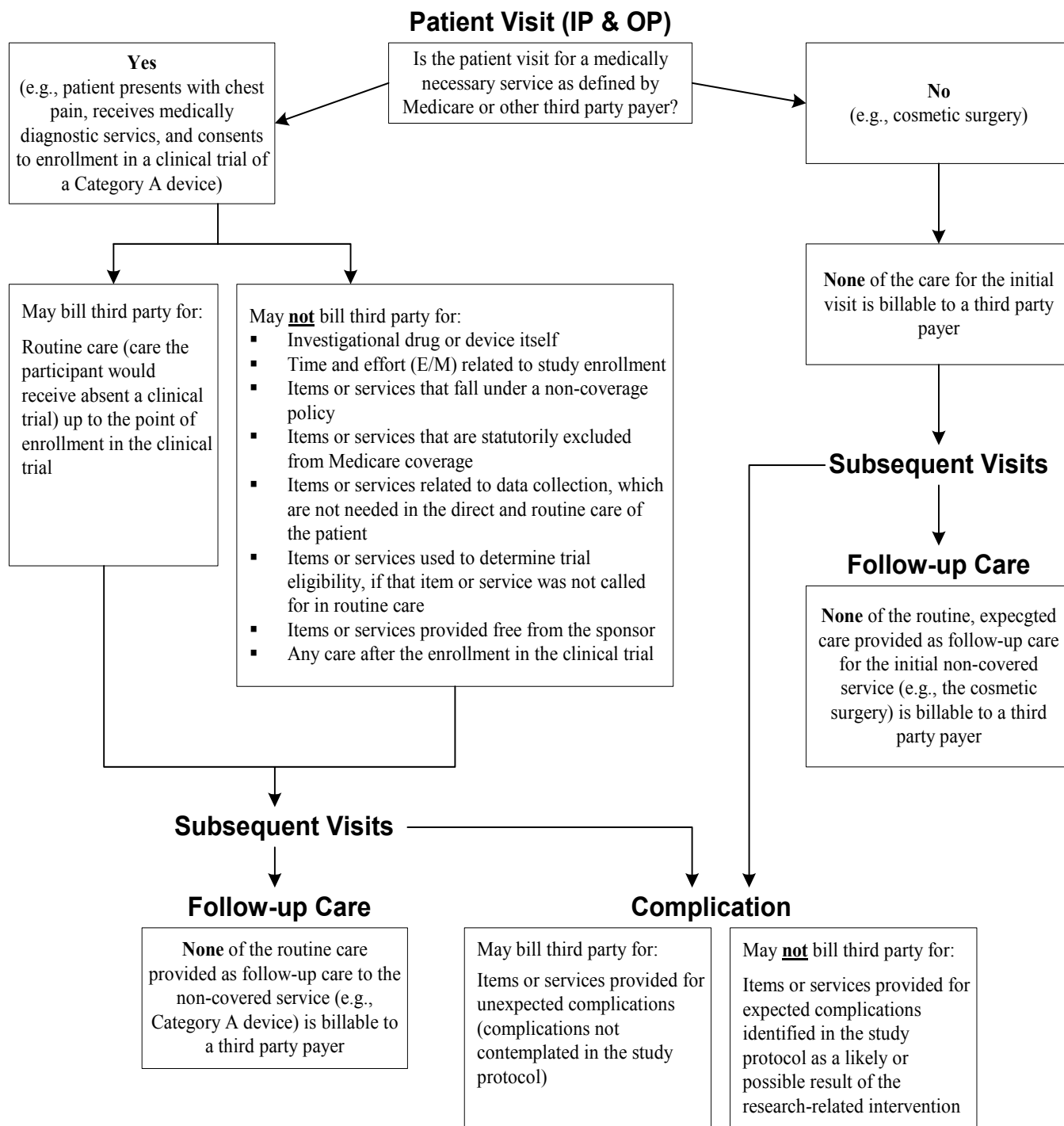
Initial Visit: In this case the patient was seeking a service that is not a medically reasonable and necessary service under most third party payers. No part of the service is billable.

Subsequent Visit: The items and services surrounding the cheek implant (device) are not billable such as procedures, office visits, anesthesia, history and physical, operating room, supplies, etc. None of the services related to the implantation of the device are billable, nor is any of the subsequent care because it does not meet the “medically reasonable and necessary” standard. Unexpected complications are covered.

No Reimbursement Allowed Algorithm

(This algorithm must be used in conjunction with the narrative information in the Medicare National Coverage Decision. It is not intended to stand alone.)

Clinical trials for which no reimbursement is allowed are trials in which the items, devices, or services, and services associated with or related to them, are not billable. In such circumstances, as for example in the installation of Category A medical devices, the only services that would be billable are those medically necessary to render a diagnosis prior to the patient's enrollment in the clinical trial. In other instances, such as cosmetic surgery itself (unlike cardiac surgery with approved or Category B devices) is not billable to Medicare.



Complications

Purpose: This section provides guidance on billing for complications that may result from participation in a clinical trial.

Use the algorithms found in Part II, Billing Guidance, of this Guide for assistance in determining whether complications are billable or not billable.

Complication—is a pathological process or event occurring during a disease that is not an essential part of the disease; it may result from the disease or from independent causes (Stedman’s Medical Dictionary). Allina Hospitals & Clinics divide these 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 meets the qualifying criteria of the NCD. If the trial does not meet the qualifying criteria, items and services furnished to treat expected complications are not billable to a third party payer.

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. Items and services furnished to treat unexpected complications are billable under the algorithms in Part II, Billing Guidance, of this Guide.

Further guidance from CMS:

The following section was taken from the CMS web site [in 2002](#).

Q. If complications occur resulting from the negligence or malfeasance of the trial sponsor (i.e., complications due to manufacturing errors, lack of proper trial oversight, etc.), will Medicare still be responsible for the costs associated with complications?

A. Yes. Medicare will cover the costs of reasonable and necessary items and services that are ordinarily covered by Medicare outside the context of a clinical trial, which are used to diagnose and treat complications arising from participation in all clinical trials, regardless of whether such complications resulted from the trial sponsor's negligence. However, as provided under section 1862(b)(2) of the Act, to the extent Medicare has paid, such payments would be conditional for purposes of Medicare being a secondary payer with respect to a liability or no fault insurance recovery that may be obtained by the participant.

Allina Requirements

Complications do not have to be documented within the Project Setup Worksheets, unless they are addressed in the Schedule of Events Worksheet, as discussed in Part IV and Part V of this Guide. However, research sites are still responsible for using their billable or non-billable Research Plan Code as required by Part VII, “Plan Codes and Other Billing Issues,” when billing for complications.

Miscellaneous Billing Issues

Purpose: This section addresses important topics not specifically addressed in other parts of the Guide.

Upcoding

Upcoding is billing for a service at a higher level than was actually delivered in order to receive increased reimbursement. A third party payer expects the bill to reflect the actual level of service provided to its member or beneficiary. An example of upcoding is using a higher code because the patient is participating in a research protocol. While it may be acceptable to bill for a service, the level cannot be increased because of the additional time needed for a patient on study. Upcoding is fraud.

Double Dipping

Double dipping is being paid for the same service twice. Double dipping constitutes fraud and is illegal. For example, a researcher is paid to conduct a qualifying clinical trial and is paid to conduct a service related to the trial (the item is specifically identified in the budget). The researcher orders a service to be performed at an Allina facility and, the research site fails to use their RPC. As a result, Allina bills the service to a third party payer. Allina has just double dipped even though it did not receive the initial payment from the sponsor.

Fair Market Value

For the purposes of this Guide, Fair Market Value is the reasonable value of the items or services provided by a research site in a clinical trial. Research-related items and services should approximate fair market value. For example, if a Principal Investigator is participating in a trial and is receiving \$5,000 per patient to collect a history and physical and to complete three data collection worksheets, the \$5,000 would seem to exceed Fair Market Value.

Bill a Third Party Payer and Hope They Pay

The SPRP identifies items and services up front so that an item or service is known to be billable or not billable to a third party payer. The process of submitting a claim to a third party “in hopes that they will pay it” is not consistent with the process required in this Guide and may be considered submitting a false claim to the third party payer.

Guidance from Industry Reps

Industry representatives sometimes provide guidance on billing and coding issues. However, this guidance may or may not be accurate. For example, a participant in a clinical trial is scheduled to receive an abdominal CT scan as part of his or her participation in the trial. Although this procedure should be coded with a specific ICD-9 code, at the sponsor’s direction a generic ICD-9 code is used instead, and the third party payer may pay for the service. While it may be acceptable to use such a code, it does not meet Allina’s coding standards and may result in non-payment because of miscoding.

Medigap, Supplemental or Multiple Insurance

Billing rules and regulations that apply to the primary payer apply to all third party payers. If the service is not covered under the primary insurance, it is not billable to any other third party payer on the patient’s account. For example, if the patient does not have a drug benefit in his or her plan, Allina will not submit a claim in order to subsequently bill the secondary payer so that Allina may receive payment. Allina considers this type of billing to be a false claim.