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Bloomberg BNA

Medical Research Law & Policy Report®

Medicare Reimbursement

A Step-by-Step Checklist for Conducting a Clinical Trial Medicare Coverage Analysis

By Nick Repucci, MPH

Introduction:

Most clinical trials contain a mixture of routine and nonroutine items and services. Often, interventional clinical trials involve testing an experimental drug or device, which is either added to—or used in place of—the standard therapy for a particular disease, as well as additional tests and procedures that are used to monitor the effects of the experimental drug or device. In clinical trials that contain both routine and nonroutine care, the standard treatment regimen that a patient would receive is modified in a manner that requires the costs for such care to be reimbursed by multiple payers—usually the sponsor of the clinical trial and the patient's insurer.

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For this reason, it is important that institutions distinguish between routine care charges and nonroutine care charges for care delivered during a patient's participation in a clinical trial. This task can be accomplished by conducting a reimbursement analysis or ''Medicare coverage analysis'' (MCA). An MCA is a detailed examination of the items and services provided in a clinical trial to determine whether they are conventionally or routinely provided to patients in a particular disease state, or if they are to be provided to the patients for study purposes only. An MCA has several important uses. It can help institutions ensure clinical trials billing compliance, avoid government scrutiny, and improve the coordination and management of clinical trials. MCAs also can help researchers develop and negotiate better clinical trial budgets and agreements, maximize recovery of research-related costs, and minimize financial burden on research participants.

Medicare coverage analysis relies on the use of Medicare coverage rules and routine care guidelines as the basis for making billing decisions, and for ensuring that claims that are to be sent to insurers are for only the routine care delivered during a clinical trial. Medicare coverage rules can be applied for all payers in order to reduce potential billing errors associated with clinical trials, because Medicare coverage rules provide the most defined standards for clinical research billing. Furthermore, the Affordable Care Act of 2010 requires private insurers to provide coverage for members who participate in clinical trials.

Figure 1

DRAFT Institution Name CONFIDENTIAL

Study Identifying Information

Study Title:

Sponsor: IND/IDE Number:
Protocol Version/Date: Phase:
Principal Investigator: Department:
IRB Number: ICF Status:
CTA Status: Budget Status:

Qualifying Clinical Trials Analysis

QCTA Criteria	Yes	No	Description
The subject or purpose of this clinical trial is the evaluation of an item or service that falls within a Medicare benefit category (e.g., drugs and biologics, physicians' services, diagnostic tests, etc.) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids, etc.).			This item or service under evaluation falls into the Medicare benefit category of…
This clinical trial is not designed exclusively to test toxicity or disease pathophysiology. It has therapeutic intent.			The primary objective of this clinical trial is… (Study Protocol, Section X.X)
This clinical trial enrolls patients with diagnosed disease.			This clinical trial enrolls patients with a diagnosis of… (Study Protocol, Section X.X)
This clinical trial has the regulatorily required, seven desirable characteristics of clinical trials, or is deemed to be highly likely to have such characteristics.			This clinical trial is operating under IND # XXXXX.
This is a qualifying clinical trial.			

Routine Care / Clinical Practice Guidelines:

Issues of Note:

PI Signature _____ **Date** _____

1 of 1 MCA Template v1.0 Narrative

There are three Medicare coverage rules, in particular, that provide guidance and restrictions on reimbursement for care provided during clinical trials: 1) 42 C.F.R. § 413.90—a regulation that has been in place since 1966 specifying that ''costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs;'' 2) Medicare's Clinical Trial Policy [National Coverage Determination for Routine Costs in Clinical Trials (NCD 310.1)]—a Medicare coverage rule that was introduced in 2000, last revised in 2007, and outlines coverage rules for routine costs in ''qualifying'' clinical trials; and 3) regulations on category B investigational device exemptions (IDE) found in 42 C.F.R. §§ 405.201-405.215, 411.15, and 411.406. In addition to these regulations, there are important Subject Injury and Medicare Secondary Payor rules that dictate what is covered in the case of research-related injury. Medicare also requires the use of particular Healthcare Common Procedure Coding System (HCPCS) modifiers on claims to help the Medicare contractor or fiscal intermediary identify—and distinguish between—investigational and routine care provided during a clinical trial. (For the purposes of this article, however, we will focus solely on how to conduct an MCA.)

There are several questions that must be answered when determining whether or not (and how) a research-related claim should be sent to Medicare or a private insurer. With an MCA, several of these questions can be answered in advance—saving providers time and money, and ensuring that false claims are not being made. However, conducting an MCA is not always an easy task. It can require a substantial amount of research on the part of the coverage analyst, and it demands a great degree of due diligence. An MCA is, in fact, a series of three analyses: 1) a determination of the ''qualifying'' status of the research study in question [i.e., whether or not the study meets all four qualifying criteria of Medicare's Clinical Trial Policy (NCD 310.1)]; 2) a determination of the routine nature of the items and services provided during the clinical trial (i.e., are the items and services that are part of the study

   ISSN 1539-1035

considered routine/standard care, or are they for research purposes only?); and 3) a determination of the billable status for those items that are considered routine care (i.e., does Medicare reimburse for them?). The following step-by-step checklist can be used as a guide to help conduct an MCA.

Step-by-Step Instructions:

1. Gather essential documentation.

The following documents provide the basic information needed for coverage analysis:

- Clinical trial protocol (if available, the approved, current version);
- Laboratory/radiology-specific sub-protocol or instructions (if applicable);
- Informed consent form (if available, the approved, current version);
- Clinical Trial Agreement (CTA) (if available, the fully executed version) or Notice of Award (NOA) (if applicable);
- Food and Drug Administration (FDA) status of investigational item (investigational new drug application (IND), IDE, exemption documentation) (if applicable); and
- Itemized study budget (if available, the sponsor-approved, current version).

Clinical trial (or ''study'') protocols and subprotocols (e.g., additional laboratory- or radiology-specific protocols) describe in detail the trial eligibility criteria; the schedule of events; the medications, dosages, and safety information; the length of study, and a number of other important, predefined study methods and materials. Such protocols are ''manuals'' for investigators to use when conducting the trial. For the purposes of conducting an MCA, important information found in the study protocol includes:

- Study title, protocol version and date;
- IND/IDE information;
- Items and services (study schema or schedule of events);
- Researcher tasks and protocol requirements;
- Study purpose and objectives;
- Study population, disease state, and patient eligibility; and
- Study sponsor information.

The informed consent form provides detailed study information in a manner that is easily understood by the volunteer research subject. For the purposes of conducting an MCA, important information found in the informed consent form includes:

- Items and services (which sometimes are not specified in the study protocol); and
- Financial information (e.g., items provided at no cost to participants and language related to payment for research-related injuries).

The clinical trial agreement is the contract between the study sponsor and the institution. It describes the terms and conditions of the relationship between the two parties, and it is a binding legal document. For the purposes of conducting an MCA, important information found in the clinical trial agreement includes:

- The name and contact information of the study sponsor;
- An itemized study budget and payment schedule (The study budget may be a separate document from—or may be appended to—the clinical trial agreement.);
- Specific items or services provided—or paid for—by the sponsor (not included in the study budget); and
- Subject injury and indemnification language.

The FDA status of the investigational item documents its approval for use in the study. The FDA status can be in correspondence from the FDA or from the sponsor. For the purposes of conducting an MCA, important information found in these documents includes an:

- IND or IDE number;
- IND exemption letter; or
- FDA Expanded Access determination.

2. Determine whether the study is a qualifying clinical trial.

Using a template like the one shown in Figure 1 can be useful when making a determination of whether or not a particular study qualifies for Medicare coverage of its routine costs, per NCD 310.1. Making such a determination requires the coverage analyst to examine the above-mentioned essential documents for information that will help answer the following three questions.

1) Is the subject or purpose of the clinical trial an evaluation of an item or service that falls within a Medicare benefit category?
2) Does the clinical trial have therapeutic intent?
3) Does the clinical trial enroll patients with diagnosed disease?

A clinical trial must meet these three requirements in order to receive Medicare coverage of routine costs. However, these three requirements, alone, are not sufficient to qualify a clinical trial for Medicare coverage of routine costs. Qualifying clinical trials also must meet the following seven desirable characteristics of clinical trials, or be deemed by the Agency for Healthcare Research and Quality (AHRQ) to be highly likely to have such characteristics:

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.

Figure 2

DRAFT Institution Name CONFIDENTIAL

The intent of this document is to provide information to help determine parties responsible for the payment of items and services associated with this study. Additional review may be necessary.	IRB NUMBER TITLE																	COMMENTS
		Cycle 1			Cycle 2			Cycle 3			Cycle 4			Cycles 5-17#			Pre-progression	Post-progression	
ITEMS AND SERVICES	Pre-Study	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	Wk 14	Wk 15	Off-Treatment Follow-up ε	Off-Treatment Follow-up ε	
Informed Consent	X																		
Inclusion/Exclusion Criteria	X																		
History and Physical Exam	X	X			X			X			X			X			X	X	
Weight and Performance Status	X	X			X			X			X			X			X	X	
Baseline Abnormalities Assessment	X																		
Disease Assessment	X												X				X	X	
Toxicity Notation		X			X			X			X			X			X	X	
Intake Calendar □					X			X			X			X					
CBC/Differential/Platelets	X	X			X			X			X			X			X	X	
Total Billirubin	X	X			X			X			X			X			X	X	
LDH	X	X			X			X			X			X			X	X	
AST/ALT (SGOT/SGPT) & Alkaline Phosphatase	X	X			X			X			X			X			X	X	
Serum Creatinine	X	X			X			X			X			X			X	X	
Materials for Pathology Review	X																		
Bone Marrow Aspiration/Biopsy δ	X												X				X		
CT neck/chest/abdomen/pelvis (diagnotic w/contrast) α	X												X				X		
PET Scan/CT β	X												X						
Tumor Specimen per Study Protocol Section 15.1	X		Xγ																
Blood per Study Protocol Section 15.1 ЖҖ	X		X		X												X		
Optional Core Needle Biopsy per Study Protocol Sections 7.4 and 15.1 (Day 8 of Cycle 1) μ			X																
Study Drug X (Days 1-7) (PO)		X			X			X			X			X					
Concomitant medications		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Adverse Events / Serious Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			

KEY: **M:** Bill Medicare **S:** Bill Study Sponsor/Account **NB:** Not billable to Medicare

Notes:
δ Repeat bone marrow biopsy to be obtained to confirm CR if screening bone marrow evaluation was positive or indeterminate. Only required if other criteria for CR have been met.
α Diagnostic quality CT scans of the chest, abdomen, pelvis and neck are to be performed at baseline, the completion of the 4th, 8th, 12th and 16th cycles (between Days 14 and 21) or at the end of treatment if the patient is taken off study prior to completing 17 cycles of therapy.
β PET/CT will be performed prior to treatment and at the completion of Cycle 4 (or earlier if the pt is taken off study prior to completing Cycle 4). PET/CT can be performed instead of separate imaging at baseline and during Cycle 4 if the CT portion is of diagnostic quality.
γ Day 8 tumor biopsy is required if patient consents. Only sites that are able to support the cost of the Day 8 biopsy are allowed to participate in requesting consent for the Day 8 specimen submission.
ЖҖ Blood for correlatives will be collected pre-treatment, Day 8, Day 22 and end of protocol treatment if patient consents.
ε Patients will be followed every 4 months for 2 years from the time of registration.
Treatment and tests will continue at these same intervals until protocol treatment ends.
□ CRA will review Intake Calendar at each visit (see Study Protocol Appendix 19.2).
μ Only sites that are able to support the cost of the Day 8 biopsy may participate in requesting consent for the Day 8 specimen.

1 of 1 MCA Template v1.0 Coverage Grid

Deemed clinical trials include:

- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), AHRQ, Centers for Medicare & Medicaid Services (CMS), Department of Defense (DOD), and Veterans Administration (VA);
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;

ISSN 1539-1035

- Trials conducted under an IND reviewed by the FDA; and
- Trials that are exempt from having an IND under 21 CFR § 312.2(b)(1).

If a clinical trial meets these qualifying criteria—including the three above-mentioned requirements and the seven desirable characteristics of clinical trials (or is deemed to be highly likely to have such characteristics)—the clinical trial will receive Medicare coverage of its associated routine costs.

Note: The Medicare Clinical Trial Policy (NCD 310.1) ''does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies (LMRPs) or the regulations on category B investigational device exemptions (IDE) found in 42 CFR §§ 405.201-405.215, 411.15, and 411.406.'' For device studies, institutions should adhere to these regulations and obtain preauthorization from their Medicare Administrative Contractors for payment of study-related routine costs.

3. Identify all items and services that are part of the clinical trial.

Identify all items and services by examining the study protocol and informed consent form. Recreate the schedule of events or study schema, and include all arms, visit dates, items and services, and any other important information indicating the frequency and degree of items and services provided. This exercise should result in the creation of a coverage grid, and look similar to a detailed budget for the trial. See Figure 2.

It is important to always review the entire study protocol to identify items and services that may not be listed in the schedule of events. Also, review the informed consent form to ensure that the items and services are congruent with the research protocol; note any discrepancies. On the grid, place an X in the cells on the visit date when the item is to occur. Shade the cells where there is no item or service provided during that visit date; do not leave any cells blank. Make the grid as detailed as possible to ensure that nothing is overlooked. For example, the schedule of events in the study protocol may only list ''CT Scan,'' but the protocol narrative may specify ''CT Abdomen & Pelvis W/Contrast.'' This detail is critical for coding and billing purposes, as well as for distinguishing between CT scans that are considered routine care versus those that are performed for research purposes only.

a. Creating coverage 'codes'

Different institutions use different codes to distinguish between items and services that are billable to Medicare, items and services that are not billable to Medicare, and items and services that are covered by the trial sponsor. Many institutions use the following three codes.

S indicates:

- Items or services that are capable of generating charges in the institution's billing system, for which the trial sponsor is compensating the research site;
- Items or services provided by the trial sponsor at no cost to the research site or study subjects [e.g., the investigational item or service, itself (unless otherwise covered outside of the clinical trial)]; and
- Items or services that are provided solely for research purposes (i.e., to satisfy data collection and analysis needs), are not used in the direct clinical management of the patient, and are not covered by Medicare.

M indicates:

- Items or services that are considered routine or conventional care, typically provided absent a clinical trial and covered by Medicare, and for which the sponsor has *not* promised to pay the research site;
- Items or services needed solely for administering the investigational item or service (e.g., infusion services for delivering a non-covered chemotherapeutic agent);
- Items or services for reasonable and necessary clinical observation following the administration of the investigational item or service, for the prevention of complications, or for the diagnosis or treatment of complications; and
- Items or services that are covered under local medical review policies (LMRPs).

NB indicates:

- Items or services that are for research purposes only but do not generate charges in the institution's billing system (e.g., informed consent, adverse events); and
- Items or services that are not separately billable from a covered item or service that may or may not be provided during the same visit (e.g., vital signs, height and weight, etc.).

4. Identify all items and services that are reimbursed by the sponsor or provided by the sponsor at no cost to the research site or study subjects.

Once all of the items and services that will be provided during the clinical trial are identified, begin populating the grid. There is no particular order required when populating the grid, but we recommend starting by identifying the items and services that are reimbursed by the sponsor or provided by the sponsor at no cost to the research site and study subjects. First identifying the items and services that are reimbursed by the sponsor or provided by the sponsor at no cost has at least two clear benefits:

1) Finding the necessary information to support sponsor coverage determinations is easier than finding evidence for Medicare coverage; and

2) Sponsors often promise to pay for all or most items and services provided in a trial, regardless of whether the items and services are covered by Medicare.

When sponsors promise to pay for an item or service that is also covered by Medicare, or if the informed consent form indicates, for instance, that there are ''no costs for participation,'' the items and services cannot be billed to Medicare. In this case, the coverage grid can quickly be completed.

Figure 3.

DRAFT | Institution Name | CONFIDENTIAL

The intent of this document is to provide information to help determine parties responsible for the payment of items and services associated with this study. Additional review may be necessary.	IRB NUMBER TITLE																COMMENTS
		Cycle 1			Cycle 2			Cycle 3			Cycle 4			Cycles 5-17#				
ITEMS AND SERVICES	Pre-Study	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	Wk 14	Wk 15	Pre-progression Off-Treatment Follow-up ε	Post-progression Off-Treatment Follow-up ε	
Informed Consent	X																		
Inclusion/Exclusion Criteria	X																		
History and Physical Exam	X	X			X			X			X			X			X	X	
Weight and Performance Status	X	X			X			X			X			X			X	X	
Baseline Abnormalities Assessment	X																		
Disease Assessment	X												X				X	X	
Toxicity Notation		X			X			X			X			X			X	X	
Intake Calendar ▫					X			X			X			X					
CBC/Differential/Platelets	X	X			X			X			X			X			X	X	
Total Bilirubin	X	X			X			X			X			X			X	X	
LDH	X	X			X			X			X			X			X	X	
AST/ALT (SGOT/SGPT) & Alkaline Phosphatase	X	X			X			X			X			X			X	X	
Serum Creatinine	X	X			X			X			X			X			X	X	
Materials for Pathology Review	X																		
Bone Marrow Aspiration/Biopsy δ	X												X				X		
CT neck/chest/abdomen/pelvis (diagnotic w/contrast) α	X												X				X		
PET Scan/CT β	X												X						
Tumor Specimen per Study Protocol Section 15.1	S		Sγ																These items are for research purposes only per Study Protocol, Sections 7.4 and 15.1. They can not be billed to Medicare.
Blood per Study Protocol Section 15.1 ЖĶ	S		S		S												S		
Optional Core Needle Biopsy per Study Protocol Sections 7.4 and 15.1 (Day 8 of Cycle 1) μ			S																
Study Drug X (Days 1-7) (PO)		S			S			S			S			S					This item is provided by the Sponsor per Study Protocol, Section 3.1 a, d.
Concomitant Medications		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Adverse Events / Serious Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			

KEY: **M:** Bill Medicare **S:** Bill Study Sponsor/Account **NB:** Not billable to Medicare

Notes:

δ Repeat bone marrow biopsy to be obtained to confirm CR if screening bone marrow evaluation was positive or indeterminate. Only required if other criteria for CR have been met.

α Diagnostic quality CT scans of the chest, abdomen, pelvis and neck are to be performed at baseline, the completion of the 4th, 8th, 12th and 16th cycles (between Days 14 and 21) or at the end of treatment if the patient is taken off study prior to compl

β PET/CT will be performed prior to treatment and at the completion of Cycle 4 (or earlier if the pt is taken off study prior to completing Cycle 4). PET/CT can be performed instead of separate imaging at baseline and during Cycle 4 if the CT portion is o

γ Day 8 tumor biopsy is required if patient consents. Only sites that are able to support the cost of the Day 8 biopsy are allowed to participate in requesting consent for the Day 8 specimen submission.

ЖĶ Blood for correlatives will be collected pre-treatment, Day 8, Day 22 and end of protocol treatment if patient consents.

ε Patients will be followed every 4 months for 2 years from the time of registration.

Treatment and tests will continue at these same intervals until protocol treatment ends.

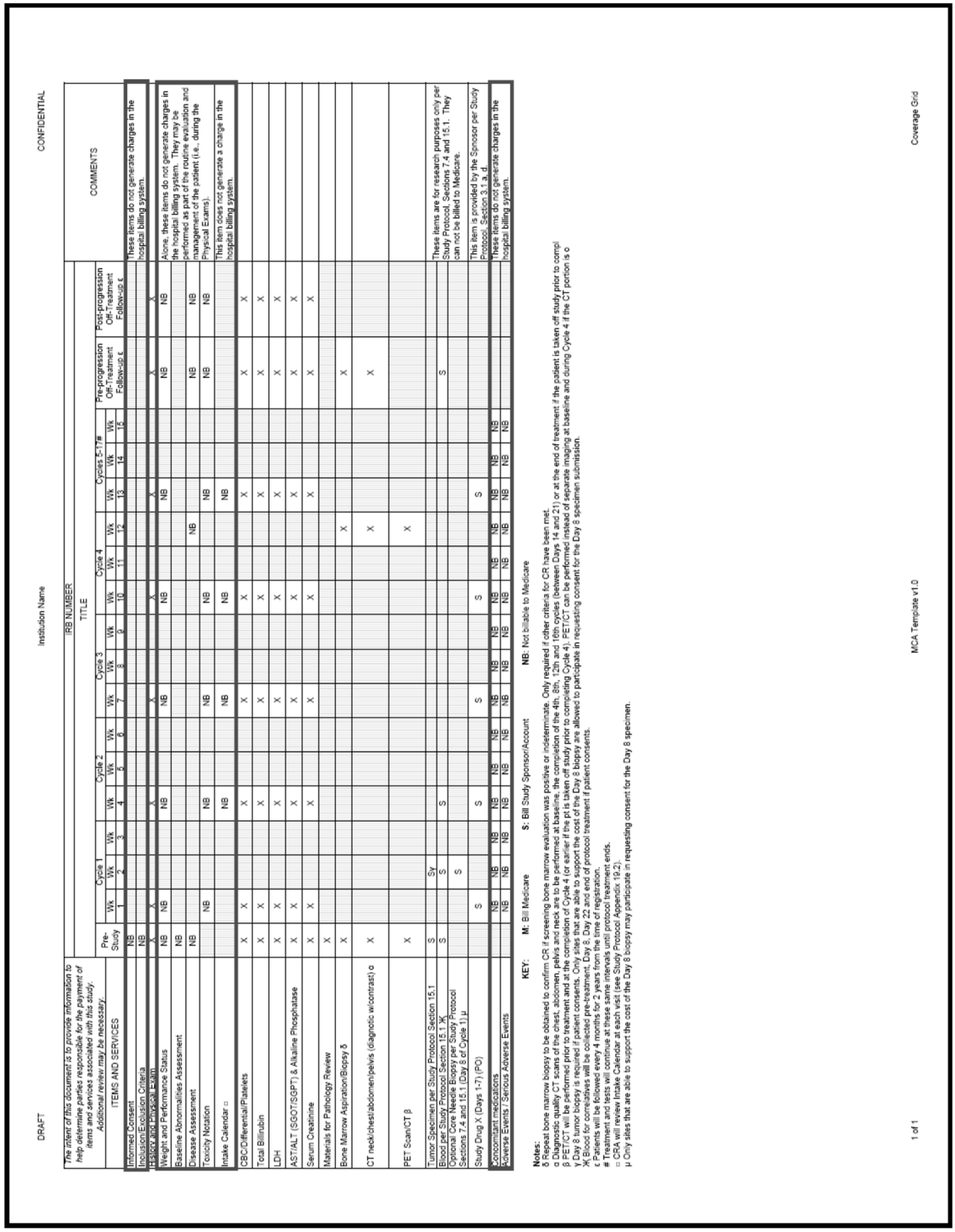
▫ CRA will review Intake Calendar at each visit (see Study Protocol Appendix 15.2).

μ Only sites that are able to support the cost of the Day 8 biopsy may participate in requesting consent for the Day 8 specimen.

1 of 1 | MCA Template v1.0 | Coverage Grid

 MRLR ISSN 1539-1035

Figure 4.



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Institution Name

IRB NUMBER

TITLE

The intent of this document is to provide information to help determine parties responsible for the payment of items and services associated with this study. Additional review may be necessary. ITEMS AND SERVICES	Pre-Study	Cycle 1		Cycle 2			Cycle 3			Cycle 4			Cycles 5-17#			Pre-progression Off-Treatment Follow-up ε	Post-progression Off-Treatment Follow-up ε	COMMENTS
		Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	Wk 14	Wk 15			
Informed Consent	NB																		These items do not generate charges in the hospital billing system.
Inclusion/Exclusion Criteria	NB																		
History and Physical Exam	X	X			X			X			X			X			X		
Weight and Performance Status	NB	NB			NB			NB			NB			NB			NB	NB	Alone, these items do not generate charges in the hospital billing system. They may be performed as part of the routine evaluation and management of the patient (i.e., during the Physical Exams).
Baseline Abnormalities Assessment	NB												NB						
Disease Assessment	NB															NB	NB		
Toxicity Notation		NB			NB			NB			NB			NB			NB	NB	
Intake Calendar □					NB			NB			NB			NB					This item does not generate a charge in the hospital billing system.
CBC/Differential/Platelets	X	X			X			X			X			X			X		
Total Billirubin	X	X			X			X			X			X			X		
LDH	X	X			X			X			X			X			X		
AST/ALT (SGOT/SGPT) & Alkaline Phosphatase	X	X			X			X			X			X			X		
Serum Creatinine	X	X			X			X			X			X			X		
Materials for Pathology Review	X																		
Bone Marrow Aspiration/Biopsy δ	X											X				X			
CT neck/chest/abdomen/pelvis (diagnotic w/contrast) α	X											X				X			
PET Scan/CT β	X												X						
Tumor Specimen per Study Protocol Section 15.1	S		Sy																These items are for research purposes only per Study Protocol. Sections 7.4 and 15.1. They can not be billed to Medicare.
Blood per Study Protocol Section 15.1 Ж	S		S		S											S			
Optional Core Needle Biopsy per Study Protocol Sections 7.4 and 15.1 (Day 8 of Cycle 1) µ			S																
Study Drug X (Days 1-7) (PO)		S			S			S			S			S					This item is provided by the Sponsor per Study Protocol. Section 3.1.a, d
Concomitant medications		NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB			These items do not generate charges in the hospital billing system.
Adverse Events / Serious Adverse Events		NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB			

KEY: **M:** Bill Medicare **S:** Bill Study Sponsor/Account **NB:** Not billable to Medicare

Notes:

δ Repeat bone marrow biopsy to be obtained to confirm CR if screening bone marrow evaluation was positive or indeterminate. Only required if other criteria for CR have been met.

α Diagnostic quality CT scans of the chest, abdomen, pelvis are to be performed at baseline, the completion of the 4th, 12th and 16th cycles (between Days 14 and 21) or at the end of treatment if the patient is taken off study prior to compl

β PET/CT will be performed prior to treatment and at the completion of Cycle 4 (or earlier if the pt is taken off study prior to completing Cycle 4). PET/CT can be performed instead of separate imaging at baseline and during Cycle 4 if the CT portion is o

γ Day 8 tumor biopsy is required if patient consents. Only sites that are able to support the cost of the Day 8 biopsy are allowed to participate in requesting consent for the Day 8 specimen submission.

Ж Blood for correlatives will be collected pre-treatment, Day 8, Day 22 and end of protocol treatment if patient consents.

ε Patients will be followed every 4 months for 2 years from the time of registration.

Treatment and tests will continue at these same intervals until protocol treatment ends.

□ CRA will review Intake Calendar at each visit (see Study Protocol Appendix 19.2).

µ Only sites that are able to support the cost of the Day 8 biopsy may participate in requesting consent for the Day 8 specimen.

1 of 1

MCA Template v1.0

Coverage Grid

In order to determine which items and services are being paid for or provided by the sponsor, examine the clinical trial agreement payment section and budget (if provided). Explore the study protocol, particularly the section that discusses the investigational item, where the sponsor discusses, for instance, who is supplying

the investigational drug and how the product should be handled.

Additionally, scan the informed consent form for a section that discusses costs to study subjects (e.g., ''Important Financial Information''), and identify items and services that are promised by the sponsor. For each item or service that is being paid for or provided by the sponsor, replace the 'X' on the coverage grid with an 'S'. In the Comments, cite to the document that supports the determination that the sponsor is paying for or providing the item or service. See Figure 3.

5. Identify all nonbillable items and services.

As noted above, nonbillable items and services include:

1) Items or services that are for research purposes only but do NOT generate charges in an institution's billing system (e.g., informed consent, adverse events, concomitant medications, etc.); and
2) Items or services that are not separately billable from a covered item or service that may or may not be provided during the same visit (e.g., vital signs, height and weight, etc.).

Because the coverage grid is modeled (in part) after a study protocol's schedule of events, it will list items and services that are important to researchers who must accurately follow the study protocol and complete case report forms (CRFs) for the trial sponsor. But the costs of these items and services are not captured in an institution's billing system. While they are for research purposes only, they should be marked as ''NB'' in the coverage grid, and not ''S,'' because they are not items and services that can be coded or billed to an insurer. A sponsor's detailed budget may or may not list these nonbillable items and services individually. Their costs often are captured under ''coordinator fees'' or a similar line item, and they are reimbursed by the sponsor based on the time spent performing the tasks.

Nonbillable items and services often are easy to identify. Common nonbillable items and services in clinical trials include: informed consent, eligibility criteria, adverse events/serious adverse events, and concomitant medications. Other nonbillable items and services that are routinely identified in the study protocol and coverage grid, but require further consideration, include: height and weight, vital signs, performance status, patient-reported quality of life assessments, and health status questionnaires, scales, assessments, inventories, and batteries. These items and services often are included in a clinical assessment and are not separately billable. Therefore, they also should be marked ''NB'' in the coverage grid, and their comments should state that they are not separately billable from a covered item or service. See Figure 4. If unsure whether or not these items and services are billable on their own, consult with a coding and billing specialist.

6. Determine whether or not the remaining items and services are routinely provided outside of the clinical trial to patients with the same disease as the study subjects.

It is not always easy to determine whether an item or service provided in a clinical trial is considered routine care. Not only is there geographic or regional variation in routine care—meaning, the care you receive in Atlanta may be different than the care you receive in Boston for the same illness—it also often varies between neighboring institutions and even among clinicians in the same practice. This phenomenon has been the focus of health services research for many years, and it remains a contentious issue in the medical community. Licensed physicians (generally) are free to make treatment decisions based on their own medical judgment, and do not necessarily base those decisions on evidence-based clinical practices or consensus among their peers.

Thus, the PI ultimately is responsible for making the final determination of whether or not a particular item or service provided in the clinical trial is considered routine care. Otherwise, the coverage analyst should utilize clinical practice or treatment guidelines, clinical consensus statements, local clinical protocols or practice standards, and current peer-reviewed journal articles (including comprehensive reviews and meta-analyses) to make routine care determinations.

For each item or service that is considered routine care, replace the ''X'' on the grid with an ''M,'' cite the clinical practice guidelines or other supporting document(s), and identify and cite the Medicare coverage policies or LMRPs that provide billing justification. See Figure 5. These policies can be found in the *Medicare Benefit Policy Manual*, the *Medicare Claims Processing Manual*, and the *Medicare National Coverage Determinations (NCD) Manual*. Additionally, you can search the Medicare Coverage Database (MCD) for National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), local articles, and proposed NCD decisions.

7. Determine whether or not any remaining nonroutine care items and services are covered by Medicare.

If an item or service is not considered routine care, the analyst should review the clinical trial protocol and informed consent form to determine whether the items or services are needed solely for administering the investigational item or service (e.g., infusion services for delivering a noncovered chemotherapeutic agent) or for reasonable and necessary clinical observation following the administration of the investigational item or service, for the prevention of complications, or for the diagnosis or treatment of complications. As noted above, the Medicare Clinical Trial Policy covers these nonroutine items and services, as well as items and services that are covered under LMRPs or the regulations on category B IDEs. Lastly, CMS has made National Coverage Determinations for specific studies involving anticancer chemotherapies that are used off-label (e.g., CMS NCD 110.17—Anti-Cancer Chemotherapy for Colorectal Cancer). It is important that the coverage analyst make an effort to determine whether any nonroutine items and services are specifically covered by these or other special policies.

   ISSN 1539-1035

Figure 5.

FINAL | **Institution Name** | CONFIDENTIAL

The intent of this document is to provide information to help determine parties responsible for the payment of items and services associated with this study. Additional review may be necessary.	IRB NUMBER																				COMMENTS
	TITLE																					
		Cycle 1			Cycle 2			Cycle 3			Cycle 4			Cycle 5			Cycle 6-17#					
ITEMS AND SERVICES	Pre-Study	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	Wk 14	Wk 15	Wk 16	Wk 17	Wk 18	Pre-progression Off-Treatment Follow-up ε	Post-progression Off-Treatment Follow-up ε	
Informed Consent	NB																					These items do not generate charges in the hospital billing system.
Inclusion/Exclusion Criteria	NB																					
History and Physical Exam	M	M			M			M			M			M			M			M	M	According to the NCCN Clinical Practice Guidelines for Non-Hodgkins Lymphomas (v1.2012), physical examination is considered routine care at clinical workup and for response assessment for patients with Non-hodgkins lymphoma. It is covered by Medicare per Medicare Benefit Policy Manual Chapter 15, Section 30.
Weight and Performance Status	NB	NB			NB			NB			NB			NB			NB			NB	NB	Alone, these items do not generate charges in the hospital billing system. They may be performed as part of the routine evaluation and management of the patient (i.e., during the Physical Exams).
Baseline Abnormalities Assessment	NB																					
Disease Assessment	NB												NB							NB	NB	
Toxicity Notation		NB			NB			NB			NB			NB			NB			NB	NB	
Intake Calendar □					NB			NB			NB			NB			NB					This item does not generate a charge in the hospital billing system.
CBC/Differential/Platelets	M	M			M			M			M			M			M			M	M	According to the NCCN Clinical Practice Guidelines for Non-Hodgkins Lymphomas (v1.2012), these laboratory tests are considered routine care at clinical workup (Pre-Study) for patients with Non-hodgkins lymphoma. Laboratory tests at other time points are for response assessment and to detect complications. They are covered by Medicare per NCD 190.15 (CBC), and per Medicare Benefit Policy Manual Chapter 15, Section 60.1
Total Bilirubin	M	M			M			M			M			M			M			M	M	
LDH	M	M			M			M			M			M			M			M	M	
AST/ALT (SGOT/SGPT) & Alkaline Phosphatase	M	M			M			M			M			M			M			M	M	
Serum Creatinine	M	M			M			M			M			M			M			M	M	
Materials for Pathology Review	M																					
Bone Marrow Aspiration/Biopsy δ	M												M							M		
CT neck/chest/abdomen/pelvis (diagnotic w/contrast) α	M												M							M		According to the NCCN Clinical Practice Guidelines for Non-Hodgkins Lymphomas (v1.2012), these scans are considered routine care for initial staging and response evaluation for patients with Non-hodgkins lymphoma. They are covered by Medicare per NCDs 220.1 (CT) and 220.6.5 (PET).
PET Scan/CT β	M												M									
Tumor Specimen per Study Protocol Section 15.1	S		Sγ																			These items are for research purposes only per Study Protocol, Sections 7.4 and 15.1. They can not be billed to Medicare.
Blood per Study Protocol Section 15.1Ж	S		S		S															S		
Optional Core Needle Biopsy per Study Protocol Sections 7.4 and 15.1 (Day 8 of Cycle 1) μ			S																			
Study Drug X (Days 1-7) (PO)		S			S			S			S			S			S					This item is provided by the Sponsor per Study Protocol, Section 3.1 a, d.
Concomitant medications		NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB			These items do not generate charges in the hospital billing system.
Adverse Events / Serious Adverse Events		NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB			

KEY: **M:** Bill Medicare **S:** Bill Study Sponsor/Account **NB:** Not billable to Medicare

Notes:
δ Repeat bone marrow biopsy to be obtained to confirm CR if screening bone marrow evaluation was positive or indeterminate. Only required if other criteria for CR have been met.
α Diagnostic quality CT scans of the chest, abdomen, pelvis and neck are to be performed at baseline, the completion of the 4th, 8th, 12th and 16th cycles (between Days 14 and 21) or at the end of treatment if the patient is taken off study prior to completing 17 cycles of therapy.
β PET/CT will be perfomed prior to treatment and at the completion of Cycle 4 (or earlier if the pt is taken off study prior to completing Cycle 4). PET/CT can be performed instead of separate imaging at baseline and during Cycle 4 if the CT portion is of diagnostic quality.
γ Day 8 tumor biopsy is required if patient consents. Only sites that are able to support the cost of the Day 8 biopsy are allowed to participate in requesting consent for the Day 8 specimen submission.
Ж Blood for correlatives will be collected pre-treatment, Day 8, Day 22 and end of protocol treatment if patient consents.
ε Patients will be followed every 4 months for 2 years from the time of registration.
Treatment and tests will continue at these same intervals until protocol treatment ends.
□ CRA will review Intake Calendar at each visit (see Study Protocol Appendix 19.2).
μ Only sites that are able to support the cost of the Day 8 biopsy may participate in requesting consent for the Day 8 specimen.

1 of 1 | MCA Template_080712b.xls | Grid Template (2)

For each item or service that is covered under these or other special state or federal coverage policies, replace the "X" on the grid with an "M" and document the rationale and coverage policy to provide billing justification. For any noncovered items or services—that are not routinely provided to patients outside of a clini-

cal trial and for which there is no special coverage policy—that ''hit'' the institution's billing system and are not explicitly covered by the sponsor, as documented in the budget and/or clinical trial agreement, replace the ''X'' on the grid with an ''S'' and negotiate payment from the sponsor. These items and services must not be billed to Medicare or other insurers.

Helpful Tips to Remember:

- Coverage analysis gets easier and faster with time.
- Carefully examine the essential documents.
- Read the entire clinical trial protocol; don't rely only on the schedule of events.
- Go for the ''low-hanging fruit'' first.
- Engage physicians, coders, and billers when there are questions.
- Bookmark useful websites for future reference.
- Become familiar with Medicare coverage policies, especially NCD 310.1 and Chapter 15 of the *Medicare Benefit Policy Manual*.
- Re-use citations when appropriate.

   ISSN 1539-1035