

**SAMPLE – FOR DISCUSSION PURPOSES ONLY**

**Medicare Coverage Analysis**

Study Title:	
Sponsor:	
Protocol No.	
IRB No.	
Principal Investigator:	
Department:	
Coordinator:	
Site(s):	
Anticipated Enrollment:	
Study Type (drug or device):	
Medicare Coverage Analysis Review Prepared By:	
Initial Completion Date:	
Documents Reviewed:	

**Background:** A Medicare Coverage Analysis (MCA) is necessary for all clinical trials involving pharmaceutical interventions in which any items and services are or may be invoiced to Medicare. The MCA involves determining the underlying eligibility of the study for Medicare coverage and reviewing the clinical events specified in the Protocol (and outlined in the Protocol Billing Grid) to determine which items or services may be billed to Medicare. Medicare’s Clinical Trial Policy only allows coverage of routine costs during qualifying clinical trials. Medicare will not cover costs that are (1) paid for by the sponsor, (2) promised free in the informed consent document, (3) not ordinarily covered by Medicare, or (4) solely to determine trial eligibility or for data collection or analysis.

**A. MEDICARE QUALIFYING CRITERIA (not applicable to device trials) <sup>1</sup>**

1. Does the investigational item or service fall within a Medicare benefit category (e.g., physician services, diagnostic tests)?

Yes - Continue to item 2.

No – **STOP. Trial is not a qualifying clinical study.**

2. Has the item or service been statutorily excluded (e.g., cosmetic surgery, hearing aids)?

Yes – **STOP. Trial not a qualifying clinical study.**

No – Continue to Item 3.

<sup>1</sup> CMS National Coverage Determination for Routine Costs in Clinical Trials (CMS Manual 310.1)

**SAMPLE – FOR DISCUSSION PURPOSES ONLY**

**Medicare Coverage Analysis**

3. Does the trial have a therapeutic intent (i.e., not designed exclusively to test toxicity or disease pathophysiology)?
- Yes - Continue to item 4.
- No - **STOP. Trial is not a qualifying clinical study.**
4. Do subjects have diagnosed disease (i.e., subjects are not healthy volunteers)<sup>2</sup>?
- Yes - Continue to item 5.
- No - **STOP. Trial is not a qualifying clinical study.**
5. Is the study deemed - does the trial fall within at least one of the following categories (please check appropriate box)<sup>3 4</sup>?
- a. Is the trial funded by NIH, CDC, AHRQ, CMS, DoD, or the VA?  Yes.  No.
- b. Is the trial supported by a center or cooperative group that is funded by the NIH, CDC, AHRQ, CMS, DOD, or the VA?  Yes.  No.
- c. Is the trial conducted under an Investigational New Drug (IND) application reviewed by the FDA?  Yes.  No.
- d. Is the trial exempt from IND application under 21 CFR 312.2 (b)(1)?
- Yes.  No.
- Yes – Continue to Item 6.
- No – **STOP. Trial is not a qualifying clinical trial.**

6. If you answered “Yes” to Items 1, 3, and 4, “No” to Item 2, and were able to check at least one “Yes” box under Item 5, *the drug trial qualifies for Medicare coverage.*  Yes.  No. If yes, continue to Routine Cost Review on page 3.

<sup>2</sup> Trials for diagnostic interventions may enroll healthy subjects in a control group.

<sup>3</sup> Meaning the trial is “deemed” to automatically meet the “seven desirable characteristics” of qualifying clinical trials.

<sup>4</sup> The local Medicare contractor should be contacted to determine whether items and services will be covered in that geographic area on trials that do not meet the “deemed” criteria.

**Medicare Coverage Analysis**

**B. ROUTINE COST REVIEW (not applicable to device trials)**

1. Is the item or service generally available to Medicare beneficiaries (i.e., has a Medicare benefit category, not statutorily excluded, does not fall under Medicare national non-coverage decision)?

Yes - Continue to Item 2.

No - **STOP. Item or service is not covered as routine cost.**

2. Is the item or service one of the following:

a. The investigational item or service OR

b. Item or service used solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the subject OR

c. Item or service is provided by the sponsor free of charge to any enrollee in the trial.

Yes - **STOP. Item or service is not covered as routine cost.**

No - Continue to Item 3.

3. Is the item or service one of the following:

a. Item or service typically provided absent a clinical trial (e.g., conventional care)?

Yes.  No.

b. Item or service is required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapy drug)?

Yes.  No.

c. Item or service required for the clinically appropriate monitoring of the effects of the investigational item or service or the prevention of complications from item or service?

Yes.  No.

d. Item or service is medically necessary for diagnosis or treatment of complications arising from provision of an investigational item or service?

Yes.  No.

**Medicare Coverage Analysis**

Yes – Continue to Item 4.

No – **STOP. Item or service is not covered as routine cost.**

**4. The item or service satisfies the requirements for *routine costs*.  Yes.  No**

Prepared By:

\_\_\_\_\_  
[INSERT NAME]

Date: \_\_\_\_\_

Submitted to Billing Compliance Office By:

\_\_\_\_\_  
[INSERT NAME]

Date: \_\_\_\_\_

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