

## Medicare Coverage Analysis (MCA) Template for Clinical Trials

Field	Details
<b>Sponsor</b>	[Insert Sponsor Name]
<b>Protocol Title</b>	[Insert Study Title]
<b>Protocol Number</b>	[Insert Protocol Number]
<b>Principal Investigator</b>	[Insert PI Name]
<b>Study Site</b>	[Insert Institution Name]
<b>IND/IDE Number (if applicable)</b>	[Insert IND or IDE #]
<b>Is this a Qualifying Clinical Trial (QCT)?</b>	[Yes/No – see section below]

### Regulatory & Policy Background

Medicare coverage for clinical trial services is governed by the following:

- **Medicare National Coverage Determination (NCD) 310.1 – Routine Costs in Clinical Trials**
  - <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=1>
- **Medicare Benefit Policy Manual, Chapter 14 (Section 310.1)**
  - <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf>
- **ClinicalTrials.gov Registration Requirements**
  - <https://prsinfo.clinicaltrials.gov/>
- **CMS Frequently Asked Questions on Clinical Trial Policy**
  - <https://www.cms.gov/medicare/coverage/determinationprocess/downloads/8b3QandA.pdf>

### Qualifying Clinical Trial (QCT) Determination

To qualify for Medicare coverage under NCD 310.1, a clinical trial must meet the following **three requirements**:

1. Evaluates a Medicare benefit:  
☐ Yes
2. Not designed solely to test toxicity or pathophysiology:  
☐ Yes
3. Has therapeutic intent:  
☐ Yes

**One of the following must also apply:**

- ☐ Funded by NIH, CDC, AHRQ, CMS, DOD, or VA
- ☐ Conducted under IND/IDE reviewed by FDA

- ☐ Trial is exempt from IND/IDE requirements
- ☐ Approved by CMS through national or local coverage process
- ☐ Registered on ClinicalTrials.gov prior to enrolling first participant

**If all applicable boxes are checked, the trial qualifies for Medicare coverage.**

### Billing Grid / Budget Matrix Example

#### Legend:

- R** = Research-only (not billable to Medicare)
- C** = Covered by Medicare (standard of care)
- S** = Sponsor-covered
- M** = Medicare conditional (with documentation)
- B** = Billable to patient/insurance

Procedure / Service	Visit 1	Visit 2	Visit 3	Medicare Status	Notes / Justification
Physical Exam	C	C	C	C	Routine baseline/monitoring exam
CBC w/ Diff	R	C	R	Mixed	Baseline for eligibility only
Investigational Drug	S	S	S	S	Non-covered item, sponsor-supplied
CT Scan (Chest)	C	R	R	Mixed	1st scan SOC; subsequent are research
EKG	C	C	R	Mixed	Standard for cardiac risk
Surveys/Questionnaires	R	R	R	R	No clinical care value
Optional Biopsy	R			R	Optional, not medically necessary

### Documentation and Justification

- **SOC Justifications:** Refer to NCCN guidelines, clinical practice standards, or prior Medicare coverage decisions.

- **Research-Only Activities:** Clearly identify procedures done solely for research endpoints.
- **FDA & CMS Guidance:** Ensure appropriate documentation for IND/IDE status and therapeutic intent.

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### Compliance & Billing Considerations

Requirement/Area	Notes
Informed Consent Language	Must explain billing responsibilities
Subject Injury Language	Should explain what happens if injured
Coverage Determination Documentation	Retain QCT checklist and ClinicalTrials.gov info
Coding Requirements	Use Q0 modifier and Z00.6 diagnosis code

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### Signature and Approval

Role	Name	Signature	Date
PI / Sub-I			
Coverage Analyst			
Budget/Contract Admin			

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