Medicare Billing for Research and Clinical Trials

Previously, Medicare generally did not pay for any of the costs associated with the care of Patients who were enrolled in a clinical trial. In June 2000, Bill Clinton issued an Executive Memorandum requiring the Medicare program to expand coverage for Medicare beneficiaries to include routine costs of certain qualifying clinical trials.

Clinical Trials National Coverage Determination (NCD)

Provides Medicare coverage for “routine costs” of “qualifying clinical trials” when the routine costs are otherwise billable to Medicare outside a clinical trial. There are 10 criteria a research study must meet to be considered a “qualifying clinical trial.”

CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

Ten Criteria for “Qualifying Clinical Trial”

1. The premise or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category.*

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 to have a proper control group.

4. The principal purpose of the trial must be to test whether the intervention potentially improves the participant’s health outcomes.

5. The trial must be well supported by available scientific, medical information, or it must be intended to clarify or establish the health outcomes of interventions already in common clinical use.

6. The trial must not unjustifiably duplicate existing studies.

7. The trial design must be appropriate to answer the research question being asked in the trial.

8. The trial must be sponsored by a credible organization or individual capable of executing the proposed trial successfully.

9. The trial must be in compliance with federal regulations relating to the protection of human subjects.

10. All aspects of the trial must be conducted according to the appropriate standards of scientific integrity.
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.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been “deemed” to be highly likely to have the above-listed three qualifying criteria and seven desirable characteristics of clinical trials.

“Deemed Trials” – Inherently have these seven desirable characteristics

- funded by NIH, CDC, AHRQ, DOD, VA
- supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, DOD, VA
- conducted under an investigational new drug application (IND) reviewed by the FDA
- exempt from having an IND under 21 CFR 312.2(b)(1)
- lawfully marketed drug, not for new indication, not for new labeling,
- not new route of administration or dose, not for new advertising,
- does not alter risks, conducted under IRB review

What Are “Routine Costs”? or, what clinical items or services provided in a “qualifying clinical trial” are covered by Medicare?

Routine Costs Defined
Includes all items and services that are otherwise generally available to Medicare Beneficiaries.

- There exists a benefit category
- It is not statutorily excluded
- No National Non-Coverage Decision

That are provided in either the experimental or the control arm of a clinical trial

The Principal Investigator is responsible for identifying which services are billable to third party payers and which services will be covered by the research sponsor or grant funds.

Routine Costs 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, 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.

**Routine Costs Do Not Include:**
- The investigational item or service itself, unless otherwise covered outside of the clinical trial;
- 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; and
- Items and services customarily provided by research sponsor free of charge for enrollees in the trial.

(CMS Manual 310.1. Routine Costs in Clinical Trials.)

**Guidelines for Compliant Billing**

1. Perform a “Billing Coverage Analysis” before the study budget is developed, the Clinical Trial Agreement (CTA) is negotiated and signed, and before any subject is registered in the trial.
2. Determine who are the potential payers for trial services.
3. Create a “Billing Grid.”
4. Carefully follow policies/procedures for the registration and tracking of all research subjects.
5. Notify all physician groups, hospitals, laboratories, or other entities that may provide clinical services to an enrolled research subject.
6. Identify services as ‘Standard of Care’ versus ‘Research’ when ordering tests or providing services.
7. Reconcile bills/invoices with information on the Billing Grid before submission to Medicare or Insurance Companies.

**Documents for Compliant Billing**

- Study Protocol
- Analysis of Billing Coverage (or coverage analysis)
- Contract Trial Agreement (CTA)
- Study Budget
- Informed Consent

**Remember:**

- Do not bill for services the sponsor is paying for.
- Do not bill for services promised as free.
- Do not bill for services that are for research purposes only.
- Do not bill for services in a research study that is not designed to have therapeutic benefit.
- Only bill for services that have no external funding source and are medically necessary.

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**Medicare Qualifying Trial**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the investigational item or service fall into a Medicare benefit category?</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Does the study include therapeutic intent?</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Does the study enroll Patients with diagnosed disease?</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Is the study a “deemed trial”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the study a qualifying clinical trial?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>(Answers to question 1-4 must be yes for the trial to qualify)</em></td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Medicare Items and Services Decision Flow Chart

START

Is the item paid for by the sponsor or promised free in the ICF?

YES → The item is not billable to Medicare

NO

Is the item given to detect and/or prevent complications from the Investigational Product?

YES

NO

Is the item required solely for the provision of the investigational item or service?

YES

NO

Does a Medicare NCD or LCD limit coverage of the item?

YES

NO → The item is billable to Medicare

NO

Is the item conventional care for the study population?

YES

NO

Does a Medicare NCD or LCD limit coverage of the item?

YES

NO → The item is not billable to Medicare

YES

The item is billable to Medicare
# Medicare Billing Grid Sample

<table>
<thead>
<tr>
<th>Service</th>
<th>Code</th>
<th>Baseline Visit</th>
<th>Infusion 1</th>
<th>2wk visit</th>
<th>Infusion 2</th>
<th>12 week visit</th>
<th>24 week visit</th>
<th>Comments (rationale for payor choice)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE</td>
<td>M</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M</td>
<td></td>
<td>Standard Care for patients with this diagnosis absent of clinical trial</td>
</tr>
<tr>
<td>Drug 123</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Investigational product supplied by Sponsor</td>
</tr>
<tr>
<td>Infusion</td>
<td>M</td>
<td>M</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Clinically necessary to monitor effects of the Drug</td>
</tr>
<tr>
<td>CBC</td>
<td>M</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>M</td>
<td></td>
<td></td>
<td>Standard Care and research related</td>
</tr>
<tr>
<td>UA</td>
<td></td>
<td></td>
<td></td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td>Test done for data collection related to trial</td>
</tr>
<tr>
<td>USN</td>
<td></td>
<td>S (ICF)</td>
<td></td>
<td>S (ICF)</td>
<td></td>
<td></td>
<td></td>
<td>Noted in the ICF as paid by Sponsor</td>
</tr>
<tr>
<td>Pt Diary</td>
<td>N/A</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NB</td>
<td>Include in budget as staff time to discuss and educate subject</td>
</tr>
</tbody>
</table>

S = Sponsor  
ICF = Free in ICF (S)  
M = Medicare/Insurance