Clinical Research Billing Compliance Frequently Asked Questions

Identifying when study services can billed to Medicare or Insurance/Health Plan

1. Can Health Insurance/Health Plan/a third party payor be billed for items/services related to a clinical study?

Items and services provided to a patient related to his/her participation in a clinical study may be billed to the patient and his/her Health Insurance/Health Plan if certain conditions are met. Items/services billed to insurance that are related to a study should be those items that are routinely provided to patients not participating in a study. Do not bill insurance for anything that is not "reasonable and necessary."

2. What are the conditions that must be met to bill the patient or Health Insurance/Health Plan/a third party payor for study-related services?

The study-related item or service may be billed to the patient or Health Insurance/Health Plan/third party payor if it is not paid by the study sponsor or promised free to the patient in the informed consent, and it either:

- Qualifies for coverage under applicable Medicare rules if it is a government payor, or
- Qualifies for coverage under applicable State law and private payor contracts if it is a private payor

3. What clinical research items/services may be billed to the patient and her/his Medicare, Medi-Cal, or other government payors?

Clinical research items/services may be billed to Medicare, Medi-Cal, or other government payors if the item/service is not paid by the study sponsor, or promised free to the patient in the informed consent, and it either:

Is a "routine cost" of a Qualified Clinical Trial (See FAQ #3),

Would have nevertheless been provided and covered as reasonable and necessary care to the patient for prevention, diagnosis, or treatment absent the clinical trial, OR

Is for diagnosis and treatment of complications or injuries arising from participation in the research, and care of such complications or injuries is not promised to be paid or paid by the study sponsor for other subjects in the study.

4. What clinical research items/services may be billed to a patient's private third party payor (e.g. Aetna, Blue Cross, Blue Shield, etc.)?

Clinical research items/services may be billed to the patient's private third party payor if the item/service is not paid by the study sponsor or promised free to the patient in the informed consent, AND:

The study is a Phase 1-4 therapeutic cancer trial (see California Health and Safety Code Section 1370.6; Cal. Ins. Code § 10145.4),

The commercial payor has pre-authorized the item/service for coverage, as a research-related item/service,

The commercial payor's coverage terms otherwise provide coverage for the item/service when provided related to research, OR

Expanded Access, Compassionate Use, HUD.

5. What qualified clinical trial costs are not billable to the study subject or his/her insurance and must be paid by study sponsor?

The following qualified clinical trial costs are not billable to the study subject or insurance, and should be paid by the study sponsor or covered by other funding sources:

1. Any item/service that is:
    - promised free in the informed consent or
    - customarily provided by the research sponsor free of charge for any enrollee in the trial
2. The investigational item/service that is the objective of the clinical trial, unless it is otherwise covered outside the study or by other CMS coverage determinations (e.g., items/services solely for data collection
3. Protocol activity/items/services that are not for the direct clinical safety and management of the subject at the time of the order (e.g., consent, inclusion/exclusion labs/imaging/services, research-only protocol activity, monthly CT scans for a condition usually requiring only a single scan).

6. **Are patient care costs on an NIH-sponsored clinical study billable to Medicare?**

   Not always. Patient care costs in an NIH-sponsored study do not qualify for coverage by Medicare simply because the study is sponsored by another government agency. Medicare billing rules still apply.

7. **How do I determine if costs are billable to Medicare for an NIH-sponsored study?**

   To determine which items/services are billable, complete the coverage analysis / prospective reimbursement analysis required under the Compliance & Privacy Office Clinical Research Auditing Policy.

8. **What do I do if it is determined the services on an NIH-sponsored study are not billable to Medicare or other third party payors?**

   If unfunded patient care costs in an NIH-sponsored study are determined by the coverage analysis to not be billable to Medicare or other third party payors, the Principal Investigator must secure other appropriate sources of funding.

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

9. **Do Clinical Research Billing Compliance laws, rules, and regulations apply only to Industry sponsored studies?**

   No. Medicare and Private Payor rules and requirements for documentation, coverage, and billing DO apply to ALL clinical studies. The funding source or lack of an outside funding source (internally funded or unfunded) is not relevant. Therefore, it is important to perform an itemized coverage analysis/prospective reimbursement analysis to identify which protocol services are billable.

Resources:

- Medicare Clinical Trial Policy (National Coverage Determination 310.1)
- Medicare Claims Processing Manual, Ch. 32
- 42 CFR 405.201-405.215, 411.15, and 411.406 (for device trials)
- CMS MLN Matters SE0822 (Jan 7, 2009)
- Decision Memo for Clinical Trial Policy (CAG-00071R)

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