

# Ensuring Compliant Revenue for Clinical Research Studies: How to Know What You Can Bill

Post-Test for  
American Academy of Professional Coders  
Continuing Education Units  
from Healthcare Training Leader Webinar

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**Questions:**

1. Some items and services in a clinical research study are billable to Medicare. (true/false)
  - a. True
  - b. False
  
2. What is the National Coverage Determination (NCD) that guides clinical research billing?
  - a. NCD 7006
  - b. NCD 310.1
  - c. NCD 301.2
  - d. NCD 553
  
3. What is the first step in conducting a Coverage Analysis?
  - a. Determining what Medicare rules apply to the drugs in the study
  - b. Determining what are the routine costs
  - c. Determining whether the study qualifies for coverage under NCD 310.1
  
4. What documents are essential in performing a Coverage Analysis? (check all that apply)
  - a. Informed Consent Form
  - b. Protocol
  - c. Funding Documents
  
5. In a clinical research study, what is double billing? (fill in the blank)  
  

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6. Which of the following are potential consequences of non-compliant clinical research billing? (check all that apply)
  - a. False Claims Act violations
  - b. Civil Monetary Penalties
  - c. Exclusion from participation in federal healthcare programs
  - d. Government imposed corrective actions
  
7. What is a coverage analysis?
  - a. A Coverage Analysis is a tool that analyzes each protocol-required item and service according to Medicare coverage rules (i.e., NCD 310.1 and “all other Medicare rules”).
  - b. A Coverage Analysis is a tool that tells physicians how to take care of clinical research patients.
  - c. A Coverage Analysis is a mathematical analysis of the research billing to know how much revenue was taken in as a result of the study.

8. Which of these is NOT something that a Coverage Analysis does?
  - a. The Coverage Analysis documents the considerations, reasoning, and determinations made by the organization.
  - b. The Coverage Analysis translates the study services into the billing and claims environment.
  - c. The Coverage Analysis consolidates multiple study documents that impact payment into a single unified “source of truth.”
  - d. The Coverage Analysis is a tool to coordinate information for purposes of budgeting, claims review, auditing, and business assessment.
  - e. The Coverage Analysis instructs the physician regarding the best clinical care for the research patient.
  
9. It is best practice to analyze coverage using which payer’s coverage and billing rules?
  - a. Your state’s Medicaid
  - b. Aetna
  - c. Medicare
  - d. Blue Cross Blue Shield
  - e. Humana
  
10. Clinical reasoning and Medicare coverage will always align. (True or false)
  - a. True
  - b. False
  
11. Which of the following is NOT one of the three necessary requirements when determining whether a study qualifies for coverage?
  - a. That the item or service falls in a benefit category
  - b. That there is a minimum number of patients that will enroll in the study
  - c. That the study has therapeutic intent
  - d. That the study enrolls patients with diagnosed disease
  
12. Which of the following is a routine cost?
  - a. The investigational item itself
  - b. Labs performed for data collection/analysis purposes only
  - c. Conventional care items and services
  - d. Items and services being paid by the sponsor
  
13. What are “screening services” in Medicare rules?
  - a. Services performed to determine whether the patient is eligible for participation in the study
  - b. Services performed on asymptomatic patients

14. What should an organization do with the Coverage Analysis when there are amendments to the study documents?
- a. Nothing
  - b. Notify Medicare
  - c. Edit the coverage analysis to reflect the changes and re-analyze the added items and services, and/or update the payment terms if the funding documents are amended
15. Before the Coverage Analysis can be used for billing, what finalized documents must be harmonized with the Coverage Analysis to prevent double billing and billing for items or services promised free to the patient?
- a. The NCDs and LCDs
  - b. The Protocol and the Investigator's Brochure
  - c. The clinical guidelines
  - d. The Clinical Trial Agreement and the Informed Consent Form

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