

WHAT IS A “QUALIFYING CLINICAL TRIAL” UNDER MEDICARE?  
(NOT APPLICABLE TO DEVICE TRIALS)

1. Does the subject or purpose of the trial evaluate an item or service that falls within a Medicare benefit category (e.g., physician’s services, diagnostic tests) and the item or service is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

If you answered yes, continue to item 2. If you answered no, trial is not a qualifying clinical trial – not permitted to bill Medicare for routine costs.

2. Does the trial have a therapeutic intent (i.e. not designed exclusively to test toxicity or disease pathophysiology)?

If you answered yes, continue to item 3. If you answered no, trial is not a qualifying clinical trial – not permitted to bill Medicare for routine costs.

3. Does the trial enroll only patients with diagnosed disease as opposed to healthy volunteers? Trials for diagnostic interventions may enroll healthy patients in a control group.

If you answered yes, continue to item 4. If you answered no, trial is not a qualifying clinical trial – not permitted to bill Medicare for routine costs.

4. Answer the following to determine if the trial falls into one of the following categories deemed automatically qualified for Medicare coverage:
  - a. Is trial funded by NIH, CDC, AHRQ, CMS, DOD, or VA OR
  - b. A cooperative group that is funded by the NIH, CDC, AHRQ, CMC, DOD, or VA OR
  - c. Is trial conducted under an IND application reviewed by the FDA OR
  - d. Exempt from IND application under 21 CFR 312.2(b)(1)?

If you answered yes to any of the above in #4 the trial is “deemed” qualified for Medicare coverage of routine costs. If you answered no to all of the above in #4, trial is not a qualifying clinical trial – not permitted to bill Medicare for routine costs.

ROUTINE COSTS UNDER A MEDICARE QUALIFYING CLINICAL TRIAL  
(NOT APPLICABLE TO DEVICE TRIALS)

1. Is item or service “generally available” to Medicare beneficiaries (and the item or service is not otherwise excluded under Medicare)?

If you answered yes, continue to item 2. If you answered no, the item or service is not covered as routine cost under Medicare and should not be billed to Medicare.

2. Is the item or service characterized as one of the following:
  - a. The cost of the “non-covered” investigational item or service itself;
  - b. Item or service is used solely to satisfy data collection and analysis needs and is not used in direct clinical management of patient (e.g., monthly CT scans for a condition requiring only one CT scan);
  - c. Item or service is customarily provided by research sponsors free of charge for any study subject in the trial; or
  - d. Item or service is provided solely to determine trial eligibility.

If you answered no to all of the above statements in #2, continue to item 3. If you answered yes to any of the above statements, the item or service is not covered as routine cost under Medicare and should not be billed to Medicare.

3. Is the item or service contained within one of the following categories:
  - a. Item or service is typically provided absent a clinical trial (e.g., conventional care);
  - b. Item or service required solely for the provision of investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);
  - 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;
  - d. Item or service is medically necessary for reasonable and necessary care arising from the provision of an investigation item or service – in particular, for the diagnosis or treatment of complications.

If you answered yes to any of the above in #3, service or item qualifies for coverage as routine cost under Medicare. If you answered no to all the above in #3, the item or service is not covered as routine cost under Medicare and should not be billed to Medicare.