

# FAQ's for Qualifying Clinical Trials

## What is a qualifying clinical trial?

Medicare covers the routine costs of “qualifying clinical trials” as defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. A qualifying clinical trial (QCT) is a trial that meets the requirements set forth in Clinical Trial Policy (NCD 310.1) by the Center for Medicare and Medicaid Services (CMS). This policy delineates the requirements that a trial must meet to be designated as a QCT.

## What are the criteria for a qualifying clinical trial?

As outlined below there are three (3) mandatory criteria and seven (7) desirable characteristics to be designated a QCT.

### Mandatory Criteria:

1. The subject or purpose of the trial is the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial is not designed exclusively to test toxicity or disease pathophysiology and must have therapeutic intent.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers, although trials of diagnostic interventions may enroll healthy patients to have a proper control group.

### Desirable Characteristics

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity,

Once a trial has been determined to be a QCT, the routine costs associated with it are billable to and reimbursable by Medicare.

## What is “therapeutic intent” in a clinical trial?

Trials with therapeutic intent must have an objective/aim that assesses the effects of the intervention on patient outcome (i.e., prolongation of life, shrinkage of tumor or improvements in quality of life) and must not be exclusively designed to test toxicity or disease pathophysiology.

## What is a billing grid?

A billing grid delineates whether the items and services related to the care of a patient participating in a clinical trial are routine patients costs (i.e., items and services that a 3<sup>rd</sup> party payer would cover if the patients was not enrolled in a clinical trial) or whether they are investigational (i.e., solely for data

collection and analysis purposes and not for direct clinical management of the patient – or – for a service inconsistent with the established standards of care for the patient’s diagnosis.) All qualifying clinical trials at BCM are required to have a billing grid.

### **Why do I need a billing grid for a qualifying clinical trial?**

The billing grid facilitates billing compliance and enables coordinators and research administration to correctly identify those items and services that are for research purposes only from those that are part of routine care and therefore billable to Medicare or the patient’s provider.

### **Why do I need to evaluate if my study is a qualifying clinical trial or not?**

CMS Clinical Trial Policy requires that trials meet the qualification criteria outlined to receive reimbursement for routine costs associated with the care of subjects enrolled in therapeutic clinical trials. If a trial does not “qualify” under the Clinical Trial Policy (NCD 310.1) then the costs for all items and services related to the clinical trial are not billable to Medicare or insurance providers and must be provided by the study sponsor.

### **My studies do not enroll patients on Medicare so why should I use Medicare rules for determining coverage?**

CMS's coverage determinations are the driving force for reimbursement rules by 3<sup>rd</sup> party providers in the United States. These coverage determinations are considered the "gold standard" on which private insurance carriers base their coverage decisions. As such, the Clinical Trial Policy is the cornerstone for research billing compliance programs in academic medical institutions across the country.

### **What is a routine cost?**

Routine costs as defined by the Clinical Trial Policy are those items and services in a protocol that are billable and reimbursable to Medicare. Simply stated, routine costs include all items and services that the payer would cover if the subject was not enrolled in a clinical trial.

### **What is considered research?**

These are items and services that are not covered by Medicare including:

- 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
- items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial

### **What are NCDs (national coverage determinations) and LCD (local coverage determinations)?**

A National Coverage Determinations (NCD) is a nationwide determination set forth by the Centers for Medicare/Medicaid Services as to whether Medicare will pay for an item or service. In the absence of a NCD, an item or service is covered at the discretion of Medicare contractors based on Local Coverage Determinations (LCDs) determined by the Medicare Administrator Contract (MAC).

MACs cover geographic areas or "jurisdictions" and serve institutional provider, physicians, practitioners and suppliers. Texas, which is in Jurisdiction H, is currently served by a MAC provider named Novitas Solutions, Inc.

## Why must trials for investigational devices be sent to Medicare for billing approval?

Certain devices and/or the routine costs of qualifying device studies can be billed and reimbursed by Medicare. However, for device trials that Medicare deems as QCTS, advance designation is required prior to billing for any costs.

Documents that must be submitted to Medicare for review include: the protocol, FDA approval of an Investigational Device Exemption (IDE), copy of the IRB approval letter, the NCT number (clinicaltrials.gov registry number) and any other relevant supporting material. Medicare reviews the required information and makes a determination within 30 to 45 days as to whether the trial is a qualifying trial. (For more information visit: <http://www.cms.gov/Medicare/Coverage/IDE/>)

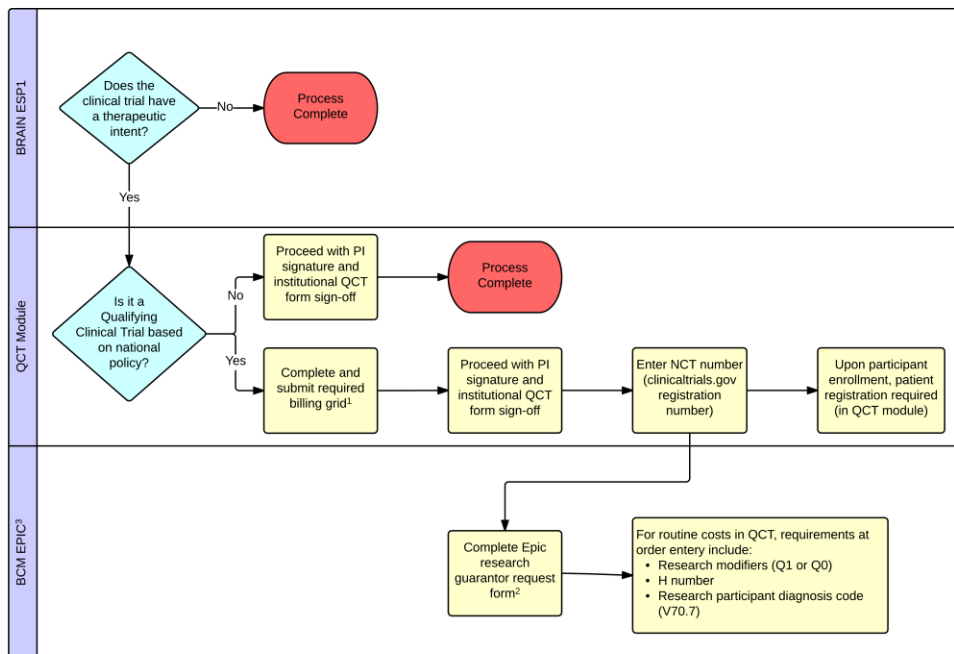
## Do all device trials have to be submitted for coverage determination?

No, not all device trials need to be submitted for coverage determination. Trials under an FDA IDE with a Category A or B determination and trials that utilize carotid artery stents under a pre-market approval or 510(K) require approval by Medicare.

## What is the Baylor College of Medicine's process for a qualifying clinical trial?



BCM Qualifying Clinical Trial (QCT) Process Map



1. Download billing grid template at [qct.bcm.edu](http://qct.bcm.edu)
2. Access Epic research guarantor request form at [qct.bcm.edu](http://qct.bcm.edu)
3. Baylor Epic requirements, please follow affiliate specific guidelines for research participant order entry

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