### MEDICARE BILLING FOR QUALIFYING CLINICAL TRIALS V. COVERAGE WITH EVIDENCE **DEVELOPMENT (CED)**

#### **JOHNS HOPKINS MEDICINE**



#### **DEFINITIONS**

Billing for Medicare's Qualifying Clinical Trials (QCT) and Coverage with Evidence Development (CED) is very similar but they are governed by different Medicare regulations. For a better understanding, here are a few key definitions:

- 1. Clinical Trial Clinical trials are a type of research that studies new tests and treatments and evaluates their effect on human health outcomes. 1
- 2. Qualifying Clinical Trial A clinical trial that met Medicare's qualifying criteria as explained in the National Coverage Determination (NCD) 310.12 and summarized in the graphic below:

## **CMS Qualifying Clinical Trial**

The item or service falls into a Medicare benefit category and it is not statutorily excluded (e.g cosmetic surgery, hearing aids)



The study has therapeutic intent



The study enrolls participants with a diagnosed disease (may also enroll healthy controls

One of these must be true for the study to be "deemed":

- · Is funded/supported by NIH, CDC, AHRQ, CMS, DOD, or VA
- supported by centers cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD, or VA
- · Has an IND number: Trial conducted under an investigational new drug application (IND) reviewed by the **FDA**
- Trial is exempt from having an IND

- 3. Coverage with Evidence Development CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data.3
- 4. Registry Under the CED paradigm some studies must participate in an approved Registry for Medicare to pay for services.3

Note: Both clinical research studies and registries must be registered on ClinicalTrials.gov. Registries are also registered in the Agency for Healthcare Quality (AHRQ).

Billing for QCT v. CED 1 Liza Rodríguez

#### BILLING FOR QUALIFYING CLINICAL TRIALS V. COVERAGE WITH EVIDENCE DEVELOPMENT

#### **Clinical Trials**

At Johns Hopkins, whether a study is qualifying or not is determined by the Office of Clinical Research Support Services (CRSS) at the time they work on the Prospective Reimbursement Analysis (PRA). The Clinical Research Billing Compliance (CRBC) staff is tasked with assuring that charges for research participants are reviewed for appropriate routing to the participant's insurance or to the research study. CRBC will add the research diagnosis and other billing indicators (modifiers, condition code 30, NCT number) to Medicare claims as required by CMS.

#### **Coverage with Evidence Development**

CMS may issue a CED if insufficient evidence exists to conclude definitively that an item or service is "reasonable and necessary." CEDs are approved by Medicare and each one has their own NCD and billing instructions. In general, CEDs are covered under one of these two conditions<sup>4</sup>:

- 1. Clinical Trial The patient participates in a CMS (Centers for Medicare and Medicaid Services) approved clinical trial.
- 2. <u>Data Collection as a Condition of Coverage</u> Also known as a "Registry", this is the mechanism that CMS uses to gather information about the procedure/service for full approval later. Registries are usually managed by a professional organization/association.

Both the approved registries and clinical trials for each CED are listed on <u>CMS's webpage</u>. A summary of the difference between billing for a QCT versus a CED is in the graphic to the right.

>Important — Bookmark the <u>Coverage with</u>
<u>Evidence Development page</u> and refer to it often.

Note that each of the CEDs has its own instructions and specific billing directions. Clinical Trials should follow the normal process of IRB submission, PRA approval, and patient enrollment in the clinical trial management system (CTMS). On the other hand, CEDs that only require Registry submissions are not in the CTMS. Registry entries are usually submitted by a member of the care/study team.

>Important – It is imperative for the care/research teams to complete and document the patient registry step. The addition of modifiers Q1/Q0 to the claims is Johns Hopkins' attestation that this step took place.

#### WHAT CAN YOU DO?

- Make sure that you are familiar with the protocol and the PRA. Carefully review the PRA before you approve it. Become familiar with who pays for services related to your study.
- Make sure that the subject receives and understands the Insurance and Research Participant Financial Responsibility Information Sheet that is part of the consent process. This form can be found in the eIRB, right below the consent form. The fact that a subject is a participant in a research study DOES NOT mean that all services are free. If the participant does not understand his/her financial responsibilities, have them meet with a financial counselor in your department.
- Make sure that you entered the participant in the CTMS before the encounter is closed in Epic and do not take them "off study" on the same date that services were provided.

# Billing for CMS QCT v. CED

QCT V. CED

- Must be billed with specific research diagnosis and other indicators
- Study must be evaluated and found to be qualifying
- The presence of the Q1/Q0 modifier is our attestation that we are billing routine care charges for a qualifying clinical trial
- Must be billed with specific research diagnosis and other indicators
- CEDs are covered under a clinical trial or registry requirement
- The CED must be listed in the CMS CED page
- The presence of the Q1/Q0 modifier is our attestation that we are billing correctly for a CED and that the Registry requirement was completed

• Make sure that Registry entries are done on time. Hopkins cannot bill Medicare if this step has not been completed.

#### References

- 1. World Health Organization. (n.d.). Clinical Trials. <a href="https://www.who.int/health-topics/clinical-trials#tab=tab">https://www.who.int/health-topics/clinical-trials#tab=tab</a> 1
- 2. CMS. (2007, July 9). NCD 310.1, Routine Costs in Clinical Trials. <a href="https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1">https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1</a>
- 3. CMS. (2014, November 20). Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development. <a href="https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27">https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27</a>
- 4. CMS. (2006, July 12). Guidance for the Public, Industry, and CMS Staff. National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development.

  https://www.cms.gov/medicare/coverage/determinationprocess/downloads/ced.pdf

Important clinical research billing information and helpful contacts are available at this web link: JHM Research Revenue Cycle Website

Questions? CLINIRESBILLING@jh.edu

12/1/2023