

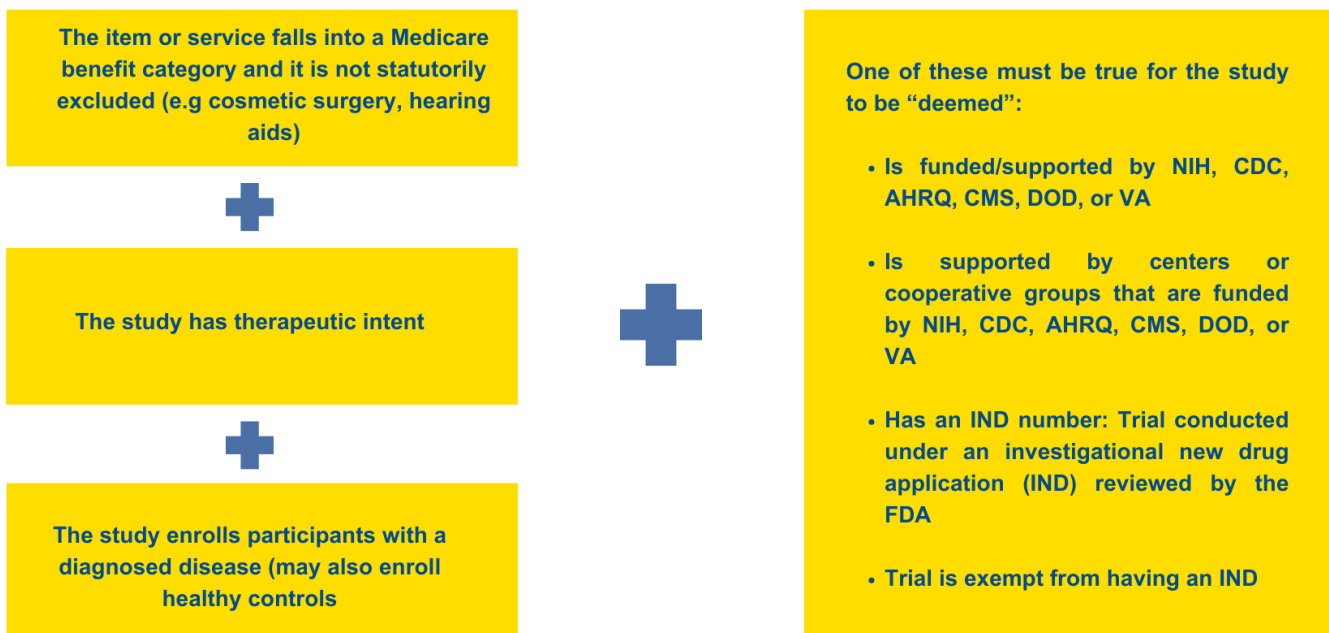
DEFINITIONS

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



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).

- 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*. https://www.who.int/health-topics/clinical-trials#tab=tab_1
2. CMS. (2007, July 9). *NCD 310.1, Routine Costs in Clinical Trials*. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1>
3. CMS. (2014, November 20). *Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development*. <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27>
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