Medicare & Clinical Trials

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Objectives

- Describe Medicare's Clinical Trial policy
- Discuss the purpose of a Medicare Coverage Analysis

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Medicare…Underlying Theme

- Medicare's definition of medical necessity stems from the SSA of 1965 (1862[a][1][A])…states **no payment** under Medicare Part A or Part B for any expenses incurred for items or services which, except for certain named exceptions "are not *reasonable and necessary* for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body part"

- Not medically necessary: a particular service is not a benefit under the defined benefit, for this diagnosis, at this time (Article for Medical Necessity –A3369- WPS, 2/1/02)

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National Coverage Determinations (NCD) & Local Coverage Determinations (LCD)

- National Coverage Determinations (NCDs): Nationwide determination of whether Medicare will pay for an item or service.

- Local Coverage Determination (LCD): Decision by a Fiscal Intermediary (FI) or Carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with §1862(a)(1)(A) of the Social Security Act (e.g., determination as to whether the service or item is reasonable and necessary).
  - Developed when there is not NCD or when there is a need to further define a NCD
  - LCD's cannot conflict with NCDS

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Medicare's (NCD) Routine Costs in Clinical Trials (310.1)

- Medicare covers "routine costs" of "qualifying clinical trials"

EXCEPT:

- Item/service excluded from coverage
- Item/service being paid for by the sponsor
- Items and services provided solely to satisfy data collection and analysis (e.g. monthly CT when condition usually requires single scan)
- Investigational item or service (unless covered outside a clinical trial)

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Qualifying Clinical Trial- Two Prong Analysis

THREE requirements:

- The subject or purpose of trial must be an evaluation of an item or service that fall within a Medicare Benefit Category and is not statutorily prohibited
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteer. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

. Deemed to be automatically qualified:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, DOD and VA
- Trials conducted under an investigational new drug application ("IND") reviewed by the FDA; and
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)…until qualifying criteria are developed and certification process established

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Desirable Characteristics

A clinical trial is a “qualifying clinical trial” if it has all 7 “desirable characteristics:”

- The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes
- 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
- The trial does not unjustifiably duplicate existing studies
- The trial design is appropriate to answer the research question being asked in the trial
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully
- The trial is in compliance with Federal regulations relating to the protection of human subjects; and
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity

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Coverage Analysis

- Reviews protocol, informed consent and draft budget
- Reviews coverage of items & services based on NCDs and LCDs
- Documents supporting guidelines for coverage (RECIST, NCCN, etc.)
- Guides in budget development
- Guide for cost section in ICF (21 CFR 50.25)

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Is the study a QCT under Medicare's Clinical Trial Policy?	**Yes** **1. Evaluation of a Medicare benefit (Drug)** **2. Therapeutic Intent (Response rates and OS)** **3. Diagnosed Disease (Breast Cancer)**
What is the investigational item or service ?	IL-2
What is the Sponsor providing?	IL-2

Item or Service	Billing Code	NCD/LCD	Comment
Brain MRI or CT	As appropriate	220.2	If clinically indicated
CT or MRI (chest, abd & pelvis	RC		Recist guideline version 1.1; NCCN v3.2013 Invasive Breast Cancer,
Hepatitis Screening	As appropriate	190.33	Medicare limitations: 1.Abnormal LFTs 2.Liver transplantation Proposed decision memo for screening for Hep C in Adults at high risk for Hepatitis C (3/4/14)
PFT's	As appropriate	L32762	This does not appear to be a screening test approved for coverage by Medicare; therefore in order to obtain coverage, the patient has to be symptomatic and the PI has to document medical necessity.
Administration of IL-2	RC	310.1	

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Pilot Coverage Analysis

- A preliminary coverage analysis will be conducted during study development to check if the items & services required should be covered by Medicare

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