Medicare & Clinical Trials

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ALLIANCE

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Objectives

- Describe Medicare’s Clinical Trial policy
- Discuss the purpose of a Medicare Coverage Analysis
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)
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
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)
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
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
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)
<table>
<thead>
<tr>
<th>Item or Service</th>
<th>Billing Code</th>
<th>NCD/LCD</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain MRI or CT</td>
<td>As appropriate</td>
<td>220.2</td>
<td>If clinically indicated</td>
</tr>
<tr>
<td>CT or MRI (chest, abd &amp; pelvis)</td>
<td>RC</td>
<td></td>
<td>Recist guideline version 1.1; NCCN v3.2013 Invasive Breast Cancer,</td>
</tr>
<tr>
<td>Hepatitis Screening</td>
<td>As appropriate</td>
<td>190.33</td>
<td>Medicare limitations: 1.Abnormal LFTs 2.Liver transplantation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Proposed decision memo for screening for Hep C in Adults at high risk for Hepatitis C (3/4/14)</td>
</tr>
<tr>
<td>PFT’s</td>
<td>As appropriate</td>
<td>L32762</td>
<td>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.</td>
</tr>
<tr>
<td>Administration of IL-2</td>
<td>RC</td>
<td>310.1</td>
<td></td>
</tr>
</tbody>
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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