Session T209

Medicare, Clinical Trials, & You

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Objectives

• Describe the principles of the Medicare program
• Describe and discuss Medicare’s clinical trial policy
• Describe and discuss Medicare’s coverage of category A and B investigational device exemptions (IDE) in the context of a clinical trial
• Describe and discuss Coverage with Evidence Development (CED)
• Discuss the role of Clinicaltrials.gov
• Describe the link between Medicare and Clinicaltrials.gov
• Identify risks associated with non-compliance
Medicare...Then & Now

1965— Congress passed legislation establishing the Medicare program as Title XVIII and Title XIX of the Social Security Act in response to specific medical care needs of the elderly

1973— Coverage expanded for certain disabled persons and certain persons with kidney disease

2000— Clinical trial policy, prior to this national coverage determination Medicare beneficiaries could not participate in clinical trials- as Medicare would not cover the costs of routine care

Then - Two parts:
- Hospital insurance (HI aka Part A)
- Supplementary medical insurance (SMI aka Part B)

Now - Four parts:
- Part A (hospital coverage)
- Part B (medical Insurance)
- Part C aka Medicare Advantage Plans (combines A, B, and perhaps D into an HMO or PPO with a private insurer)
- Part D (prescription drug coverage)
Medicare and Its Alphabetical Parts

- **Medicare Part A**—Hospital Insurance
  - Free for Medicare beneficiaries
  - *Covers*: hospital services, skilled nursing facility care, hospice and home healthcare services

- **Medicare Part B**—Supplementary Medical Insurance
  - Premium
  - *Covers*: physician and surgeon professional fees, NP, PA (etc.) fees, some preventative care services and screening tests, ER visits, outpatient treatments
Medicare and Its Alphabetical Parts (cont)

- **Medicare Part C**: Medicare Advantage Plan (was Medicare + Choice)
  - Expands beneficiaries’ options to participate in private-sector health care plans
  - A type of Medicare health plan offered by a private company that contracts with Medicare to provide you with all your Medicare part A and part B benefits
  - Medicare Advantage Plans include health maintenance organizations, preferred provider organizations, private fee-for-service plans, special needs plans, and Medicare medical savings account plans
  - If you’re enrolled in a Medicare Advantage Plan, Medicare services are covered through the plan and are not paid for under original Medicare
  - Most Medicare Advantage Plans offer prescription drug (Part D) coverage AND
    - **Will** cover routine costs of device studies
    - **Will not** cover routine costs of drug/IND studies—go to original Medicare

- **Medicare Part D**: Fee and different plans. Goal is to subsidize prescription costs not covered in Medicare part A or part B. Has a coverage gap.
How Is Medicare Funded?

- The two parts of traditional Medicare are funded in very different ways
  - Part A, which covers in-patient hospital bills, is financed by a trust fund known as the Hospital Insurance Fund (HI Fund)
    - The percent the government deducts from your paycheck—and also from your employer—is placed in the HI Fund to cover part A services
    - This payroll tax provides the bulk of the money that flows into the HI fund, which is in turn used to cover part A expenses
  - Part B, which covers doctor appointments, is run by a separate trust fund, called the Supplemental Medical Insurance Trust Fund (SMI Fund)
    - Enrollee premiums and funds from the general budget supply the SMI Fund, which then pays for part B services
Medicare Is Managed by...

- Centers for Medicare & Medicaid Services (CMS) responsible for administering these programs
  - Formerly Health Care Financing Administration (HCFA)
- Payment for services by providers/hospital are under the prospective payment system (PPS)
- Payment for clinical labs and ambulance services under fee schedules
- Contract entities—Medicare Administrative Contractors (MACs)—process claims and provide payments
Medicare Administrative Contractor (MAC)

- Private healthcare insurer that has been awarded a geographic jurisdiction to process Medicare part A & part B medical claims, durable medical equipment (DME) claims, and Medicare fee-for-service beneficiaries (FFS)
- CMS relies heavily on the MACs to serve as operational contact between the Medicare FFS program and healthcare providers enrolled in the program
- Currently there are 12 part A & B MACs
National Coverage Determinations (NCD) & Local Coverage Determinations (LCD)

Underlying theme... is the item or service *reasonable and necessary*; provided for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body party...(and falls under a Medicare benefit category)

- National coverage determinations (NCDs) are statutes: they define what is covered by Medicare
- Local coverage determination (LCD)—aka local medical review policy (LMRP)—is a decision by a Medicare contract administrator (MAC) on 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
  - Determination as to whether the service or item is reasonable and necessary
  - LCDs are developed when there is no NCD or when there is a need to further define a NCD
  - LCDs cannot conflict with NCDs
How Medicare Works With Other Insurance

Medicare Secondary Payer Rule/Coordination of Benefits

• The primary payer pays first up to the limits of coverage
  • The secondary payer pays costs the primary insurer did not cover

• CMS determines the order of payment:
  • Medicare tries to be the secondary payer
  • Complications/injuries arising out of clinical trials: In terms of subject injury language in a contract...if a sponsor offers to pay, Medicare holds them out as a liability insurance plan, and the sponsor has reporting requirements and COB
Underlying Theme... Medical Necessity

- 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)
Medicare’s Logic on Coverage

- According to Medicare—coverage is limited to items and services that are reasonable and necessary for the diagnosis and treatment of an illness or injury (and within the scope of a Medicare benefit category and not statutorily excluded)
- Routine costs are not standard of care
Not Medically Necessary

In other words... when Medicare does not pay, it does not mean the service should not be ordered or performed, nor does it mean it is not “standard of care”—it simply means Medicare does not pay.
What Is the Difference Between Medicare & Medicaid & Private/Commercial Insurance?

- Medicare—federally funded
- Medicaid—funded federally and by the state
- Private/commercial insurance—not funded by the government
Medicare and Clinical Trials—What Does This Mean?

There are three regulations that address Medicare coverage of clinical trials:

- Coverage related to investigational device exemption (IDE) studies: [https://www.cms.gov/Medicare/Coverage/IDE/index.html](https://www.cms.gov/Medicare/Coverage/IDE/index.html)
- Clinical trial policy: National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) [https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.htm](https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.htm)
- Coverage with evidence development (CED): CMS, as part of the national coverage determination (NCD), may determine coverage of an item or service only in the context of a clinical study, which typically also involves a registry
Clinical Trial Billing Errors = Compliance Risks

• Billing Medicare for items and services provided by the sponsor
• Billing Medicare for items and services that are for research purposes only
• Billing for items and services that are promised for free in the informed consent
• Billing for items and services for a study that is not a qualifying clinical trial
Coverage With Evidence Development

• CMS released an updated guidance document on November 20, 2014, that describes coverage with evidence development (CED)

  • CMS, as part of the National Coverage Determination (NCD), may determine coverage of an item or service only in the context of a clinical study
Centers for Medicare & Medicaid Services—Investigational Device Exemption (IDE)

- Finalized changes to IDE regulations in 2015—centralized approval of devices and changed MAC review and approval of IDEs
  - May still need to submit what routine items and services will be billed for MAC approval
- **Category A:** (experimental) will allow coverage of routine care items and service furnished in the study, but not of the category A device, which is statutorily excluded from coverage
- **Category B:** (non-experimental/investigational) IDE study will allow coverage of the category B device and routine items and services in the trial

Approved IDE studies: 316
Medicare Registration of IDEs

The following IDE studies have met CMS' standards for coverage. Studies with the Category A are approved for coverage of routine services only. Studies with the Category B are approved for coverage of the Category B device and related services, and routine services.

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Sponsor Name</th>
<th>NCT Number</th>
<th>IDE Number</th>
<th>CMS Approval Date</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety and Effectiveness of TactCath™ Contact Force „Sensor Enabled“ (TactCath)</td>
<td>St. Jude Medical</td>
<td>NCT03605566</td>
<td>G180149</td>
<td>2018-10-12</td>
<td>A</td>
</tr>
<tr>
<td>SEL Catheter for Ablation of Drug Refractory Symptomatic Persistent Atrial Fibrillation (PERSIST END IDE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High-Frequency Nerve Block for Post-Amputation Pain: A Pivotal Study</td>
<td>Neuron Medical, Inc.</td>
<td>NCT02211934</td>
<td>G130203</td>
<td>2018-10-12</td>
<td>B</td>
</tr>
<tr>
<td>Proposed Single Center Investigational Device Exemption: Feasibility of Endovascular Repair of Ascending Aorta</td>
<td>Baylor Research</td>
<td>NCT03322033</td>
<td>G170196</td>
<td>2018-10-12</td>
<td>B</td>
</tr>
</tbody>
</table>
Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except...
Not considered routine cost:

- 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 (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
THREE requirements:

- The subject or purpose of trial must be an evaluation of an item or service that falls 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 are:

- 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.
- 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.
The Desirable Characteristic Test

• 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 successful;
  • 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
Method to Work With Medicare & Clinical Trial
A Billing/Coverage Analysis Provides:

- Detailed review of the study
- Detailed review of who is paying for what item or service
- Detailed review and analysis of NCDs and LCDs
- Prevents financial surprises during a project
- Provides a template for budget development (if applicable)
- Provides a tool for audits
- Provides a template to “cure” errors
- A consistent methodology for research billing
- A guide for the IRB to review the cost section of informed consent (21 CFR 50.25/45 CFR 46.116)
- Provides a template of subjects’ financial liability for the ICF
## Creating a Billing Grid/Matrix

<table>
<thead>
<tr>
<th></th>
<th>Screening</th>
<th>Randomization</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclusion/exclusion</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exam</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CBC</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>EKG</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>CT scan</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study drug</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
## Sample of Coding

<table>
<thead>
<tr>
<th></th>
<th>Screening</th>
<th>Randomization</th>
<th>Wk 1</th>
<th>Wk 2</th>
<th>Wk 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>E</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT/PTT</td>
<td>S</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exam</td>
<td>PS</td>
<td>PS</td>
<td>PS</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>CBC/chem panel</td>
<td>PS</td>
<td>S</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>CT scan</td>
<td>S</td>
<td></td>
<td>S</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep B screen</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rituxan</td>
<td></td>
<td></td>
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<td>N</td>
<td></td>
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</tbody>
</table>
## Coverage Analysis

<table>
<thead>
<tr>
<th>IRB Number#</th>
<th>PAF#</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT Number: NCT01958000</td>
<td>Pending Submission</td>
</tr>
<tr>
<td>Documents reviewed: Protocol, 9/20/13, Informed Consent, Draft Budget, Letter from Sponsor with IND number</td>
<td></td>
</tr>
<tr>
<td>FDA Assigned IND number: 110,000</td>
<td></td>
</tr>
<tr>
<td>FDA Assigned IDE number:</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Is study a qualifying clinical trial under Medicare’s Clinical Trial Policy?**

Yes

<table>
<thead>
<tr>
<th>Test</th>
<th>Required at</th>
<th>Code</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT or MRI (chest, abd, pelvis) Whole body scan</td>
<td>PS at screening</td>
<td>L28516</td>
<td>See section 7.2 of study (CT or MRI (chest, abd, pelvis mandated) as is whole body bone scan)</td>
</tr>
<tr>
<td>PET Scan (whole body scan)</td>
<td>PS at screening</td>
<td>220.6</td>
<td></td>
</tr>
<tr>
<td>PFT’s</td>
<td>PS at screening</td>
<td>LCD L32762 (Novitas Soln)</td>
<td></td>
</tr>
<tr>
<td>CT or MRI (chest, abd, pelvis) For subjects receiving study medications</td>
<td>N</td>
<td>Recist guideline version 1.1; NCCN v3.2013 Invasive Breast Cancer, PI to document medical necessity</td>
<td></td>
</tr>
<tr>
<td>PT or INR/ APTT</td>
<td>CL</td>
<td>NCD 190.16/190.17</td>
<td>Medicare has specific guidelines for indication</td>
</tr>
</tbody>
</table>

### Notes:
- CT or MRI (chest, abd, pelvis) and Whole body scan are mandated as is whole body bone scan.
- PET Scan (whole body scan) is not a screening test approved by Medicare; therefore in order to obtain coverage, the patient must be symptomatic and the PI must document medical necessity.
- PFT’s require specific codes.
- CT or MRI (chest, abd, pelvis) for subjects receiving study medications require Recist guideline version 1.1; NCCN v3.2013 Invasive Breast Cancer, and the PI must document medical necessity.
- PT or INR/ APTT require specific Medicare codes.
Informed Consent

• What is promised for “at no charge” to the subject = free

• 45 CFR 46.116 and 21 CFR 50.25
  • For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

• Any additional costs to the subject that may result from participation in the research
Budget Development and Negotiations

**Sponsor**
- Contact with Medicare to register determination if IDE is a category A or category B; then register IDE with Medicare
- Budget developed for entire project
- Site specific typically for region and urban sites
- May only cover investigational services and/or services not considered SOC
- May tell site—“just bill” it is always covered
- May or may not cover costs associated with subject injury
- May want to cover co-pays or deductible
- May provide payment for insurance denials only—and request proof of denial
- May want to willing to pay for one-off costs for a particular subject or subject population

**Site**
- Budget should be developed based on Medicare coverage analysis
- Should include charge master rates or research rates; and for SAVVY sites, all other costs related to the conduct of a clinical trial
- Typically includes overhead
- Site specific by MAC
- Medicare covers routine care—this is not SOC
- Should not accept coverage for co-pays and deductible
- Probably not a good idea to bill for denials
- Should not provide an item or service free to one subject and bill all others
- Subject to Medicare rules and of course—responsible for billing errors
Ticklers

• Sponsor to provide device at no-cost; institution agrees to submit claims to third party payors=?

• Sponsor shall pay for all reasonable medical expenses incurred for the necessary medical treatment of such injury which are not covered by subject’s medical or hospital insurance or other governmental programs providing such service=?

• Anything that addresses Medicare/Medicaid or other governmental healthcare insurance=?
ClinicalTrials.gov

Trial record 1 of 1975 for: mds

Allo vs Hypomethylating/Best Supportive Care in MDS (BMT CTN 1102)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Sponsor:
Medical College of Wisconsin

Collaborators:
National Heart, Lung, and Blood Institute (NHLBI)
National Cancer Institute (NCI)
Blood and Marrow Transplant Clinical Trials Network
National Marrow Donor Program

Information provided by (Responsible Party):
Medical College of Wisconsin

ClinicalTrials.gov Identifier: NCT02016781

Recruitment Status: Recruiting
First Posted: December 20, 2013
Last Update Posted: October 4, 2018
See Contacts and Locations
Why Register?

- It is the law
- NIH funding is dependent on registration
- International Committee of Medical Journal Editors (ICMJE) requires registration for publication
- It is a requirement if you bill items or services to Medicare following the clinical trial policy (National Coverage Determination for Routine Costs in Clinical Trials [310.1])
Resources

• Medicare Coverage Related to Investigational Device Exemption (IDE) Studies
  • https://www.cms.gov/Medicare/Coverage/IDE/index.html
  • https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html
  • https://clinicaltrials.gov/ct2/manage-recs
Thank you!

Questions?

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