Health Care Compliance Association

An Inside Look at Clinical Trial Billing in a Multi-Institutional System
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Today’s Goals and Objectives

1. Complexity of regulations governing clinical trial billing
2. The University of Texas System principles and practice for clinical trial billing
3. Collaborating to develop common policies
4. Developing site-specific procedures
Understanding the Clinical Trial Billing Regulations

The Maze of Laws & Rules Governing Clinical Trials

- CMS National Coverage Determinations (NCD) Manual - Section 310.1 Routine Costs in Clinical Trials
- Medicare Claims Processing Manual, Chapter 32, Section 68 - Investigational Device Exemption
- Medicare Claims Processing Manual, Chapter 32, Section 69 - Qualifying Clinical Trials
- Medicare Network Learning Matters SE0822 - Clarification of Medicare Payment for Routine Costs in a Clinical Trial
- CMS Manual 100-2; Ch. 14 - Medical Devices
- 35 State-specific insurance regulations
- Federal False Claims Act - Title 31 USC §§ 3721 & 3729
Medicare Clinical Trial Policy/NCD

What is covered by Medicare?

- Items and services typically provided absent a clinical trial
- Items and services required for provision of an investigational item or service (e.g., administration of a non-covered chemotherapy), clinically appropriate monitoring of effects of item/service, or prevention of complication
- Items and services needed for the reasonable and necessary care arising from provision of an investigational item/service – in particular, for the diagnosis or treatment of complications arising from participation on the research protocol

What is not covered?

- Items and services provided solely to satisfy data collection & analysis needs and are not used in direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan)
- Items and services customarily provided by research sponsors free of charge for any enrollee in the trial

Medicare Clinical Trial Policy/NCD (cont.)

2007 Clarification and Expanded coverage for items/services provided in a clinical trial:

1. If the investigational item itself would be covered outside of the trial, it is still covered within the trial
   - Generally, items and services that would be covered even in the absence of the clinical trial would be covered in a qualified clinical trial, as would certain items and services needed as an ancillary to the item under investigation (e.g., drug administration or additional testing to prevent complications)

2. The investigational item could also be covered if CMS makes a separate NCD using Coverage with Evidence Development

3. Other trials may be covered if the treatments are considered reasonable and necessary by the local contractor
Medicare Clinical Trial Policy/NCD (cont.)

Now what?

- When does clinical research require qualification under the Clinical Trial Policy from local contractors?
- What standards should Medicare contractors use when evaluating a request for coverage for services furnished to clinical trial participants?
- What is covered?
  - Standard of Care ("SOC") or Usual Care Items or Services
  - Other Routine or Expanded Coverage Items or Services
- If they are covered, is it only upon contractor approval?
- Would SOC services be covered even if no approval is sought or obtained?

The NCD allows CMS to cover routine costs of a Qualifying Clinical Trial (QCT)

QCTs must pass a two part test:

- **Part 1**: Must meet 3 necessary requirements
  - **AND**
- **Part 2**: Must be one of the five types of studies

If the study is not a QCT then no items or services required by the study are billable to Medicare even if the item or service is reasonable and necessary.
QCT Part One

QCT Must Meet All 3 Necessary Requirements

1. The study must investigate an item or service that Medicare pays for
2. The study must enroll patients with a diagnosed disease
3. The study must have therapeutic intent

Studies that can be confusing

Some studies may not to be considered QCTs:

• Preventive care studies that may not be considered a Medicare Benefit:
  ➢ Genetic studies
  ➢ Chemoprevention
  ➢ Preventive Medicine
• Phase 1 Studies
  ➢ Therapeutic intent as primary vs. secondary objective
• Investigator-initiated studies
• Studies funded by government agencies not on deemed list (may be the result of an earmark in the agency’s budget)
QCT Part Two

Must be 1 of the following 5 types of research:

1. Studies funded by NIH, CDC, AHRQ, CMS, DOD, or VA
2. Studies supported by centers of cooperative groups funded by NIH, CDC, AHRQ, DOD, or VA
3. Studies being conducted under an Investigational New Drug (IND) application
4. IND-exempt studies
5. Studies done under the Coverage with Evidence Development Process

Medicare Claims Processing Guidelines

Medicare requires that claims submitted for patients enrolled in clinical trials (inpatient and outpatient) have:

1. ICD-9-CM diagnosis code V70.7 (Examination of participant in a clinical trial) reported as a secondary diagnosis for each patient visit/service associated with a clinical trial
2. Condition Code 30 (Qualified Clinical Trial) reported on the claim to inform Medicare that the service is related to a clinical trial or study
3. Investigational Device Exception (IDE) # assigned by the FDA submitted for patients on a device study for the date(s) of service that the device is implanted
4. Revenue Code 624
   - Reported on all outpatient claims even if the device is provided free of charge
   - Reported only on inpatient claims if the device is not provided free of charge
Medicare Claims Processing Guidelines (cont.)

5. Modifier Q0 to identify the investigational item or service and modifier Q1 to identify all lines that contain a routine service with the appropriate CPT/HCPCS code on outpatient claims

6. Trial name, sponsor, and sponsor-assigned protocol number must be included in the billing provider’s medical record (i.e., Informed Consent)

7. 8-digit registry # may be reported voluntarily to inform Medicare as to which qualifying trial claims are being submitted. The number can be found at [http://clinicaltrials.gov/](http://clinicaltrials.gov/)

8. Modifier FB and FC (outpatient modifiers) to report with the CPT/HCPCS procedure code when a device is furnished to the hospital at no cost/partial credit for a replaced device

Medicare Claims Processing Guidelines (cont.)

An IDE Trial requires prior approval by Medicare Contractor prior to Medicare patients being enrolled in study.

- Fiscal Intermediary (FI) requirements – The FI agrees to consider claims for device trial after review of required documents which includes:
  a. Name and description of the device
  b. Identification of the sponsor of the trial
  c. Identification of the funding agency/organization if different from sponsor
  d. A copy of the FDA approval letter (redacted letters are not sufficient)
  e. Identification of the Lead Investigator
  f. Identification of the IDE #
  g. A copy of the local hospital/organization IRB approval
Common Misconceptions

1. Medicare always pays for “standard of care” items and services
2. Medicare has paid for the service before, so it must be OK to bill for the service
3. Hospital X did it this way so we can too
4. Clinical Trial agreements are “take it or leave it” – the pharmaceutical company sponsors will not negotiate payment terms

How about non-Medicare patients?

http://www.cancer.gov/clinicaltrials/education/laws
What are the risks if we don’t get it right?

- **Inadequate reimbursement to the site**: The negotiated rate must be equitable to the service to ensure site does not lose money.
- **Double billing**: Sponsor agrees to pay for a service in the contract and the patient’s insurance is billed instead.
- **Overpayments from Sponsor**: Overpayments from sponsors may be viewed as a violation of the Anti-kickback Statute.
- The liability of False Claims and double billing fall on the shoulders of the provider submitting the claim suggesting that clinical trial sites must become more familiar with billing guidelines, regulations, and statues surrounding clinical trials.
- But more importantly, must be aware of what clinical trials are being conducted onsite and the billing arrangements involved (i.e., contracts).

Additional Risks

- Loss of accreditation, certification and federal debarment resulting in Medicare funding loss and patient load decrease
- Fines, lawsuits, disallowances, losses
- Diminished reputation
- Increased vulnerability to litigation
- Public relations issues
- Difficulty in recruiting top faculty & students
- Decrease in sponsorship and philanthropic gifts
Now That We Understand the Regulations and Some of the Risks…

What did The University of Texas do?

Overview: University of Texas System

- $12 billion annual budget; 202,240 students, and 85,200 employees
- Nine academic universities
- Six health institutions (4 medical schools)
  - UT Southwestern Medical Center (Dallas)
  - UT Medical Branch (Galveston)
  - UT Health Science Center Houston
  - UT Health Science Center San Antonio
  - UT MD Anderson Cancer Center (Houston)
  - UT Health Science Center Tyler
Overview: UT System (cont.)

- $7.7 billion for six health institutions
- $4.3 billion annual revenues from clinical enterprise
- $1.5 billion annual research expenditures
- 4 clinical translational science awards
- 5.2 million outpatient visits
- 1.5 million hospital days
- Over 7,000 providers, 50,000 total employees
- Approximately 10 million claims annually

Collaborating to develop common policies
Collaborating to develop common policies

- Clinical Research Infrastructure
- Use of Guiding Principles
- Selection of Senior Level Champions
- Demonstrates use of the hybrid model of compliance

Clinical Research Components

- Physicians and Hospitals
- Principal Investigators (PI)
- Patients
- Subjects
- Research Sponsors (Pharma/Device Industry)
- Insurance (Medicare, others)
- Payment/Recouping Costs
Traditional Resources

- Paper and manual processes
- Dependence on human intervention and interaction

Emerging Resources

Clinical Trial Management Systems

- May assist but can be costly
- Do not always interface well
- Still largely untested
Communication across cultures

UT Southwestern’s Journey

- Researchers’ input (committee experience)
- Support from the highest levels in the organization (both leadership and resources)
- Collaborative spirit and teamwork from Information Technology, Compliance, Research Administration
- Integration into overall operations of research enterprise operations
- Field value of the U. T. System Guiding Principles
Challenges

- Disparate electronic systems (medical record, billing, grants & contracts, IRB)
- Large activation energy (new policies, change management, labor intensive)
- Limited resources (financial, human)
- Perceived as intrusive and unnecessary by many physicians and scientists

Potential Opportunities

- Better negotiating position with sponsors on the clinical trials agreement
- Recouping costs and legitimate funds left on the table
- Reducing compliance risk
- The above leads to more success in our essential mission of clinical research.
Conclusion

- Technology's contribution will be critical
- Inherent tensions will not resolve on their own, we must be thoughtful and diligent
- Revenue Cycle loan to UT HSC SA for their Clinical Trial Management System (CTMS)—others may need resources.

Guiding Principles

Senior-Level Champion

“Clearly defining roles and responsibilities can assist institutions in fulfilling their legal responsibility to comply with Department requirements, removing any uncertainty as to the precise responsibility of all individuals involved in the research enterprise.”

Guiding Principles

Organization and Control Mechanisms

- Clinical Trial Management System (CTMS) or other organizational/administrative tools
- Organizational models
  - Centralized model
  - Hybrid model
  - Decentralized model

The Present & Future

Can it get more complicated?

- Personalized Medicine
- Biomarkers

- This is the present and future of clinical trials at academic medical centers (especially cancer trials)
Biomarkers

• MEDCAC Meeting 1/27/2010 - Pharmacogenomic Testing in Cancer

• Tumor genetic factors as markers and predictors to tumor growth and response to anti-cancer agents, for example:
  ➢ CYP2D6 for breast cancer patients who are candidates for tamoxifen
  ➢ KRAS for metastatic colorectal cancer patients who are candidates for cetuximab or panitumumab

• “Currently, Medicare does not have a National Coverage Determination for using such tests for diagnosis or treatment of cancer.”

• “CMS seeks guidance from the panel to inform future coverage determinations”

Developing site specific policies & procedures
Common strategies utilized in developing site specific policies/procedures:

- Develop administrative infrastructure to support clinical trial revenue cycle processes
- Consider hiring clinical trials revenue cycle subject matter specialist or Medicare Coverage Analyst
- Develop policies & procedures, including the following:
  - Determination of Qualifying Clinical Trial
  - Medicare Coverage Analysis
  - Language in the cost section of the informed consent
  - Tracking and monitoring of clinical trial participants
  - Identification and segregation of routine and research sponsored services
  - Coding and billing for clinical trial claims
- Determine roles and responsibilities
- Develop and implement an education plan
- Develop and implement an auditing and monitoring plan

Medicare Coverage Analysis

Systematic objective review of clinical trial documents (Clinical Trial Agreement, Budget, Schedule of Events, and Informed Consent) to determine the Medicare billing status of items and services that are documented in the research protocol. This includes determination of the following:

- Does the research study constitute a clinical trial that qualifies for Medicare coverage?
- Which “routine” items or services are billable to Medicare?
- Which items or services are not covered by the trial budget and may not be covered by Medicare based on national or local coverage policies?
  - Lipid Panel
  - Magnesium
  - Thyroid Function Tests
  - Coagulation Studies
  - Iron Studies

Next step is to develop the billing grid
Example Billing Grid

Protocol Name: Phase II Study of Drug ABCD in Patients in New England with Sun Deprived Syndrome

<table>
<thead>
<tr>
<th>Procedure/evaluation</th>
<th>Screen</th>
<th>Study Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Prostate Lye</td>
<td>300</td>
<td>SDC</td>
</tr>
<tr>
<td>Fertility Test</td>
<td>300</td>
<td>SDC</td>
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<tr>
<td>Hematology GDX</td>
<td>300</td>
<td>SDC</td>
</tr>
<tr>
<td>Genotyping</td>
<td></td>
<td></td>
</tr>
<tr>
<td>St. Scan Whole Abdomen Panes</td>
<td>300</td>
<td>SDC</td>
</tr>
<tr>
<td>LNC</td>
<td>300</td>
<td>SDC</td>
</tr>
<tr>
<td>CT Scan Brain</td>
<td>300</td>
<td>SDC</td>
</tr>
<tr>
<td>Thyroid Stimulating Hormone</td>
<td>300</td>
<td>SDC</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>300</td>
<td>SDC</td>
</tr>
</tbody>
</table>

**KEY**
- SOC = Standard of Care (Can be billed to a third party payer)
- RS = Research Sponsored (Not Covered by insurer, Study-Specific)

Medicare National Coverage Policy generally only covers TSH up to 2 times per year for patients with thyroid disease. Should negotiate with payer.

Local Coverage Determinations (LCD)

New LCDs as examples of the future
- LCD for MammaPrint Test - Breast Cancer Prognosis (L30376) (Palmetto GBA)
- LCD for Oncotype DX Test - Breast Cancer Prognosis (L28287) (Palmetto GBA)
- LCD L31144 - Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG® (Highmark Medicare Services)
- LCD L30536 - Cytogenetic Analysis (Highmark Medicare Services)
- LCD for GENETIC Testing (L24308) (Noridian)
Identification and tracking of study participants

- Procedures to identify and track participants in research studies should be in place throughout the entire research “revenue cycle”
  - Consent for screening
  - Enrollment
  - Patient care services identified in schedule of events
  - Patient care services provided as a result of patient being enrolled as a study participant (services provided to prevent or monitor complications, expanded care)

- What is everyone else doing?
  - Manual notifications to Patient Financial Services
  - Shared database
  - Use of unique identifiers in scheduling/billing system (i.e., Research financial class)
  - Improved interfaces between Clinical Trial Management Systems (CTMS) and Hospital Information Systems (HIS)

Segregation of routine and research sponsored patient care services

- Develop policies and procedures that ensure patient care services associated with patients who have consented for screening as well as those who have enrolled in studies are identified for appropriate billing and claims submission.

- What is everyone else doing?
  - Phone calls or “word of mouth”
  - Research specific encounter forms
  - Research Charge Codes
  - Research “Order Entry”
  - Budget and billing grid mapping to charge codes

Collaborate with current system or new system vendors for better system solutions. Be Creative!
Questions & Discussion

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Resources

U.S. National Institute of Health
- http://www.clinicaltrials.gov

Office for Human Research Protections (OHRP)
- http://www.hhs.gov/ohrp

National Cancer Institute
- www.cancer.gov

Medicare Clinical Trial Policies
- http://www.cms.hhs.gov/ClinicalTrialPolicies

CMS Manual System, Pub 100-04 Medicare Claims Processing

The Feb. 2011 meeting of the Audit, Compliance and Management Review Committee of the U.T. Board of Regents recorded webcast and materials can be viewed and downloaded here
- http://mediasite.utsystem.edu/mediasite/Viewer/?peid=ab545d3dd2d24e2eb18c861266954011d

(scroll the time bar to the 1:09:14 mark (i.e., 1 hour, 9 minutes and 14 seconds) to view the recording)
Bios

Beth Belt, MBA, CHRC, is a manager in Deloitte & Touche LLP’s National Health Sciences Regulatory Practice and has more than 25 years of experience in the health care industry, including both academic medical center and community hospital settings. Her experience includes clinical research compliance, compliance program development, Medicare billing compliance, charge description master reviews, revenue cycle operations, laboratory management, and integration of clinical, research and financial initiatives.

Prior to joining Deloitte & Touche LLP, Beth was the administrator for the Center for Clinical and Translational Research at Dana Farber Cancer Institute as well as an active participant in the Compliance Committee, a member of the Institutional Review Board, and a member of the Alliance of Dedicated Cancer Centers Compliance Committee.

Bios (cont.)

C.J. Wolf, MD, CPC, CPC-H, began his work in the UT Systemwide Compliance Office as Assistant Systemwide Compliance Officer in June of 2009.

Prior to joining the UT System, Dr. Wolf was the Director for Billing Compliance at The University of Texas M. D. Anderson Cancer Center in Houston from 2006 to 2009, where he was responsible for directing the institution’s compliance with Federal, state, and institutional billing rules and guidelines. He was a key contributor to the development of the strategic vision for: (1) billing compliance education and training; (2) conducting and overseeing billing compliance audits; (3) serving as an in-house expert on billing compliance issues; and (4) overseeing the operations of the Billing Compliance section of the Institutional Compliance Office comprised of managers, supervisors, educators, auditors, and assistants.
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