Clinical Research Billing
North Shore - LIJ Health System

September 19, 2014

YOUR MISSION | OUR SOLUTIONS
Beth Belt

Welcome and Introductions

Beth Belt

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Beth has over 15 years of experience in healthcare regulatory compliance. She has served on engagements for healthcare systems, academic medical centers, community hospitals, and renal dialysis facilities. Beth advises clients within compliance, operations, and research departments for the healthcare provider community, including development and implementation of processes associated with the clinical trial revenue cycle and related Medicare regulations.

Prior to providing compliance and research advisory services, Beth held several key positions at Dana Farber Cancer Institute, including the Administrator for the Center for Clinical and Translational Research, Project Manager for the Clinical Trial Billing Project, as well as the Billing Compliance Manager.
Welcome and Introductions

Jason Light

Jason has over 8 years of experience in clinical trials and research operations management. This is coupled with a strong background in good clinical practice, expertise in coverage analysis/budget development, and a history of recommending solid implementation plans resulting from his unique clinical perspective.

Prior to joining Huron, Jason was the Supervisor of Clinical Research and Data Coordination for the Department of Oncology at Long Island Jewish Medical Center.
Welcome and Introductions

Sumathy Sundarababu

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Agenda
Afternoon Session

1:30 - 2:00  Clinical Research 101
- Research Definitions
- Types and Goals of Clinical Trials
- Key Players of Clinical Trials

2:00 - 3:30  Research Billing 101
- Clinical Trial Policy (CTP)
- Billing and Coding Definitions
- Medicare Claims Processing Requirements
- Resources

3:30 - 4:00  Break

4:00 - 5:00  Q&A
What is Clinical Research Billing?
The research billing process (depicted on the left) is complex and requires coordination and harmonization between partnering institutions (the hospital and physician practices). The steps in the process are as follows:

- Coverage Analysis
- Budgeting and Contracting
- Identifying Research Patients
- Registration and Admission
- Charge Segregation
- Coding
- Claims Processing and Invoicing
- Study Close-out and Residual Balances
Importance of a Clinical Research Billing Compliance Program
The Importance of a Research Billing Compliance Program

Historical Perspective

Where It Began

Prior to 1994, there was minimal government enforcement of Medicare billing compliance.

1994: Healthcare fraud attracted significant national attention when Attorney General Janet Reno identified it as the Department of Justice’s (DOJ) highest priority, behind violent crime, e.g. “PATH”, “LabScam”, and non-FDA approved devices.

Concerns by the healthcare industry that allegations of providers receiving incorrect payments were based on previously accepted practices or unclear guidance from Medicare.

In response to increased fraud enforcement efforts, providers increased lobbying efforts to minimize settlements as a result of “honest billing mistakes” and to obtain clarification of the regulations.

In response to lobbying efforts related to non-FDA approved devices, the government modified its policy by extending coverage to a new class of medical devices.
The Importance of a Research Billing Compliance Program

Historical Context of Medicare and Clinical Trials

Medicare coverage of investigational devices

Rush University Settlement drew attention to the CTP


Clinical Trial Policy (CTP) with minor changes in 2007

HHS Secretary Kathleen Sebelius announced that HHS has “begun several initiatives” to address inconsistencies in clinical research billing compliance
The Importance of a Research Billing Compliance Program

Why is this important?

Public Settlements

- University of Alabama - Birmingham
  - $3.4 Million
  - 2005

- Weill Cornell Medical Center
  - $4.3 Million
  - 2005

- Rush University Medical Center
  - $1 Million
  - 2005

- Tenet Healthcare System, Norris Cancer Center
  - $1.9 Million
  - 2010

- Emory University
  - $1.5 Million
  - 2013
Importance of a Research Billing Compliance Program
Consequences of Not Having a Billing Compliance Program

Consequences

- Costs Associated With Investigation
- Civil Fines
- Criminal Penalties
- Increased Governmental Scrutiny
- Loss of Governmental Funding
- Under Billing
- Loss of Trust by Sponsors and Participants
- Costs to Implement Corrective Action Plan
Importance of a Research Billing Compliance Program

Benefits of Having a Billing Compliance Program

- Increased Revenue Opportunities
- Early Detection of Items and Services Not Covered
- Trust of Sponsors/CRO’s
- Tool to Ensure Compliant Claims Processing
Overview of the Regulations
Overview of the Regulations

Medicare’s Clinical Trial Policy (CTP)

Medicare covers the routine costs of **qualifying** clinical trials, 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.

1. Routine costs of a clinical trial include all items services that are otherwise available to Medicare beneficiaries, required for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the items or service, the prevention of complications, or needed for the reasonable and necessary care of the patient.

2. Routine costs do **not** include the investigational item or service, items or services provided solely to satisfy data collection and analysis need and that are not used in the direct clinical management of the patient, and items and services provided by the research sponsor free of charge.
Impact of the Affordable Care Act on Clinical Trials

Section 2709 applies to all approved clinical trials. An approved clinical trial, as defined in the statute, is a phase I, II, III, or IV clinical trial that relates to the prevention, detection or treatment of cancer or other life-threatening diseases that also satisfies one of three requirements:

1. The trial is **federally funded**;
2. The trial is conducted under an **investigational new drug application**; or
3. The trial is **exempt from such an investigational new drug application**.
Overview of the Regulations
Affordable Care Act

Impact of the Affordable Care Act on Clinical Trials

In a provision of the “Act,” insurers are prohibited from denying or limiting coverage for routine clinical care for individuals enrolled on a clinical trial that would otherwise be provided if the individual was not a study participant. If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer may not:

1. Deny the individual participation in the clinical trial;
2. Deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
3. Discriminate against the individual on the basis of the individual’s participation in such trial.
Overview of the Regulations
Affordable Care Act in New York

- The “Provision”
  - Preempts State laws that require additional coverage. As such, if the Health Plan is located in one of the 35 states which has enacted laws requiring additional clinical trial coverage, the Health Plan must comply with the more stringent state laws. This has implications for Health Plans in states, like New York, which do not mandate clinical trial coverage.
  - Does not apply to grandfathered health plans. Grandfathered plans are defined as any plan or coverage that an individual was enrolled in on or before March 23, 2010 (when the new health care was enacted). However the state laws do apply.

- Consumers and healthcare providers have the right to appeal when healthcare services are denied for items/services considered experimental/investigational or when routine items/services are received during clinical trials. In New York, an expedited appeal may be requested when delay in receiving services will pose a serious threat to the patient’s condition.
Institutional Decisions – Policy Discussion
When preparing to conduct Coverage Analyses (CAs) in support of a Research Billing Compliance Program, there are key discussions and decisions that an institution must make in order to be sure that the process will be implemented properly.
A Coverage Analysis is a systematic review of clinical trial related documents (e.g. study protocol, investigational brochure, Informed Consent Form (ICF), sponsor agreement, etc.) in light of CMS coverage guidelines to determine the billing status of items and services that are to be provided as part of a study. A CA is often referred to as a Billing Grid.
Institutional Decisions
Personnel and Determination of Routine Care

Key Procedural Decisions
Personnel Involved

- Who will use the analyses and in what capacity?
  - Budget Developer
  - Study Team
  - Claims Processor
  - Research Accounting

- Who will assure compliance with the analyses?
  - Center Administrator
  - Hospital Administrator
  - Compliance Officer
  - Internal Audit

Key Policy Decisions
2. Determination of Routine Care

- Routine costs in “qualifying” clinical trials include, among other things, “items or services that are typically provided absent a clinical trial (e.g., conventional care)”

- There is a debate on how one determines what is typically provided absent a clinical trial
To qualify for Medicare reimbursement, trials must meet the seven desirable characteristics outlined in the CTP. Certain trials have been “deemed” to meet these seven characteristics. These are:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD or the VA;
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD or the VA

The question is the interpretation of the term “supported” and how far NSLIJ is willing to follow the money to determine that the trial is supported by one of these agencies.
To qualify for Medicare reimbursement, trials cannot be designed exclusively to test toxicity or disease pathophysiology; there must be therapeutic intent (TI).

CMS has not defined TI and interpretations of this requirement vary based on the level of risk an institution is willing to assume.

**How will NSLIJ define TI and evaluate it in the context of a clinical trial?**

- TI stated in the primary objective
- TI determined via PI certification
- TI stated in any objective
- TI discussed in study end points

*Based on CMS’ seven desirable characteristics for a qualifying clinical trial, the principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.*
Institutional Decisions
Applicability of CMS Rules

Should NSLIJ apply the CMS rules to all payers?

Should NSLIJ apply the CMS rules to pediatric studies when making billing determinations?

- **Arguments for:**
  - The CMS clinical research billing rules are the most sophisticated in the industry.
  - CMS tends to set the industry standard for healthcare payment.
  - One set of rules creates uniformity for policies and processes.

- **Arguments against:**
  - There are occasions in which an institution has a single (or a handful) of payers that account for a large portion of the patient population and that payer has more generous rules.
  - There are studies in which the study population is primarily non-Medicare patients.
The Medicare Administrative Contractor (MAC) for NSLIJ is National Government Services.

What guidance does NSLIJ have from the Contractor about drug and/or device clinical studies? If none, should the institution ask?

If a trial does not meet the “deemed” criteria, is there a process in place for contacting the local Medicare Contractor to determine whether items and services will be covered in your geographic area (per the CMS FAQs on the Clinical Trial Policy)?

Break
Developing Leading Practices
Leading Practices
What are the Processes?

Coverage analysis development and budgeting and contracting are key components of the clinical research billing process. CAs and budgets are important tools that allow research billing reviewers to correctly process claims.

When patients are consented and enrolled they are identified in the financial system as research subjects to allow for a detailed review of claims.

Charge segregation, coding, processing of claims, and invoicing the sponsor are billing processes that take place as patients take part in the study.

As the study team completes final reports for the sponsor, accounts are balanced and closed in the financial system.
Leading Practices
Common strategies utilized

- Develop a centralized administrative infrastructure
- Implement a Clinical Trial Management System (CTMS) and Patient Billing System with Research Billing functionality
- Determine roles and responsibilities
  - Principal Investigators, Study Coordinators
  - Clinical Trials Revenue Cycle Specialist and/or Coverage Analysts
- Develop institutional policies & procedures
- Develop common definitions
- Develop and implement a formal training program
- Develop and implement an auditing and monitoring plan
NSLIJ Processes

North Shore- LIJ Health System Billing process

1. Office of Clinical Research Service performs Coverage Analysis
2. Budget is prepared for clinical trial consistent with the Coverage Analysis
3. Registration forms are utilized to route charges appropriately
4. QA review is performed on research claims
5. Expense reconciliation is performed
6. Audits are conducted through the Office of Research Compliance
7. Billing Policy “Billing Procedure for outpatient services, inpatient services and ancillary testing in clinical research protocols” (located at North Shore LIJ HealthPort- Research Policies)

Contact Clinical Research Service for billing inquiries (516 562 1003 OR 3642)
Questions / Lunch
Clinical Research 101
FDA has defined clinical investigation to be synonymous with research.

**Clinical investigation** - any experiment that involves a test article and one or more human subjects and that either must meet the requirements for prior submission to the FDA or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
**Clinical Research 101**

**Definitions**

**Test article** - any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act.

**Human subject** - an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.
Clinical Research 101
Types of Clinical Trials

- **Treatment**
  - Test new approaches to treat a disease

- **Prevention**
  - Test new approaches to prevent a disease

- **Early Detection/Screening**
  - Identify new ways to detect disease

- **Diagnostic**
  - Identify new tests or procedures to diagnose disease

- **Supportive Care**
  - Explore new ways to improve the comfort and quality of life of individuals with chronic illness

- **Compassionate Use**
  - Provide partially tested, unapproved therapeutics to a small number of patients who have no other realistic options
Clinical Research 101
Goals of Clinical Trials

- Effectiveness of Intervention to Treat a Disease
- Test Drug Formulation
- Safety of a New Drug or Device
- Exploring Combination Therapies
- Defining Dose Administration
- Evaluating Effect of Therapies on Quality of Life
For every 5,000 compounds evaluated in discovery/preclinical testing, approximately 5 enter clinical trials and 1 receives FDA approval.
Clinical Research 101
Device Development Timeline

- Concept and Design: ~12 months
- Pre-Clinical Engineering Development: 24-36 months
- Clinical Trials:
  - 510(k): 0-9 months
  - PMA: 9-36 months
- FDA Review:
  - 510(k): 3-5 months
  - PMA: 22-32 months
- Patient access: 0-24 months

http://neurotechzone.com/posts/1096
Clinical Research 101
Types of Device Trials

Categories of Devices Possibly Covered Under Medicare

- FDA Approved Through the Pre-Market Approval (PMA) Process
- Devices Cleared by the FDA Through the 510(k) Process
- FDA-Approved IDE Category B Devices
- Humanitarian Device Exemption (HDE)
- Institutional Review Board (IRB)-Approved Devices
Devices approved by the FDA through the PMA or 510(k) process are covered by Medicare.

FDA sometimes approves the device contingent on post-marketing studies being performed.

- Billing post-approval studies, e.g. carotid artery stenting (CAS), is similar to normal Category B IDE billing procedures, except that under post-approval coverage, providers must submit the PMA or 510(k) number assigned by the FDA
  - Category B Device number begins with a “G”
  - PMA (pre-IDE) number begins with a “P”
  - 510k number begins with an “I”
Clinical Research 101
Category A&B IDEs

Category A

- Experimental device
- Device is intended for use in diagnosis, monitoring, or treatment of immediately life-threatening disease or condition
- Device never covered
- Routine care costs may be covered
- Approval from Medicare Contractor required for routine cost coverage

Category B

- Non-Experimental device
- Device may be used in all types of trials
- Device may be covered
- Routine care costs may be covered
- Approval from Medicare Contractor required for device and routine cost coverage
A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

To obtain approval for a HUD, a humanitarian device exemption (HDE) application is submitted to the FDA. A HDE is similar in both form and content to a PMA application, but is exempt from the effectiveness requirements of a PMA.

Medicare has no specific rules, regulations, or instructions with regard to HUDs.
- Each Medicare contractor has different requirements for submission of HUDs and has different policies around billing HUDs.

Medicare contractors may only approve HUDs via an LCD or via an “individual consideration” for coverage granted to individual patients. In the absence of an LCD, providers may apply for coverage of individual patients only.
Non-significant risk trials that include devices which do not require an FDA-approved IDE are the responsibility of the institution’s IRB.

- Sponsor initially makes the determination that the device is non-significant risk and the IRB either confirms or rejects this decision.

Examples:
- Contact lens solutions
- Digital mammography
- Externally worn monitors for insulin reactions
- General urological catheters for short term use
- Non-implantable electrical continence devices

Medicare Contractors apply the same coverage criteria, where appropriate, to these devices as is applied to FDA-approved Category B devices.

Clinical Research 101
Key Players

Investigational Site

The clinical research site is the actual location where the patients participating in the study are seen.

Examples of research sites:
- Academic Medical Centers
- Hospitals
- Private Physician Practices
- Dedicated Research Facilities

Institutional Review Board (IRB)

- An independent committee established to review and approve research involving human subjects.
- Primary purpose is to protect the rights and welfare of the human subjects.
- Ensures that potential research-related risks are minimized and that there is full disclosure so that volunteers can make an informed decision about whether or not to participate.
- Can be local or central.
Principal Investigator (PI)

• Responsible for personally conducting or supervising the conduct of human-subjects research and for protecting the rights, safety, and welfare of the subjects enrolled in the research.

• The PI must ensure that all human-subjects research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations and institutional policies and requirements.

Sub-Investigator (Sub-I or Co-I)

• Work closely with the PI to help conduct patient screening, treatment visits, data collection, and other necessary processes throughout the duration of a trial.
Clinical Research 101

Key Players

Study Coordinator

- The clinical research coordinator is responsible for conducting the clinical trial under the supervision of the PI.
- Examples of a coordinator’s responsibilities include submitting regulatory documents, scheduling patient visits, managing patient recruitment, and coordinating monitoring visits.

Study Subject or Participant

- Patient enrolled in a clinical trial who volunteers to receive an investigational treatment.
- Participant can be diagnosed with a disease or a healthy volunteer.
- Participant must sign an informed consent (ICF) to participate.
- Participant must meet protocol inclusion/exclusion criteria to enroll.
Clinical Research 101
Key Players

Sponsor

- The organization that initiates a clinical trial.
- Ultimately responsible for management of the entire trial including:
  - Selecting qualified investigators
  - Ensuring proper monitoring of the trial
  - Ensuring that the trial is conducted in accordance with the protocol
  - Ensuring that the FDA and all participating investigators are informed of any significant new risks with respect to the study drug/device
- Types
  - Pharmaceutical, biotechnology, or medical device companies
  - Governmental agencies (ex: NIH)
  - Health care institutions such as AMCs
  - Individual researchers

Contract Research Organization (CRO)

- An organization contracted by the sponsor to assume various aspects of the clinical research process.
- CROs employ various clinical research associates (CRA), biostatisticians, medical writers, project managers, and similar clinical research professionals to support the conduct of clinical trials.
Office for Human Research Protections (OHRP)

- Provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services.
- Helps ensure this by providing:
  - Clarification and guidance
  - Developing education programs and materials
  - Maintaining regulatory oversight
  - Providing advice on ethical and regulatory issues in biomedical and social-behavioral research

Food & Drug Administration (FDA)

- Agency of the United States Department of Health and Human Services
- Responsible for protecting and promoting public health through the regulation and supervision of food, drug, and insecticides.
- In relation to clinical trials, the FDA ensures the adherence to the principles of Good Clinical Practice and adequate human subject protection.
Research Billing 101
Medicare’s current Clinical Trial Policy (CTP) as of July 9, 2007

www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html

• “Effective for items and services furnished on or after September 19, 2000 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.”

• 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 if 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 and treatment of complications from participation in the research protocol
What is covered (continued)

- If the investigational item itself would be covered outside of the trial, it is still covered within the trial.
- The investigational item could also be covered as part of a Coverage with Evidence Development Trial.
What is a Qualifying Clinical Trial?

- Purpose of the trial must be for the evaluation of an item or service with a benefit category
- Must have therapeutic intent
- Must enroll patients with a diagnosed disease
- Must be “deemed” (i.e. must meet the seven desirable characteristics defined by the CTP)
What is **not** covered?

- Items and services typically provided solely to satisfy data collection and analysis needs and are not used in the clinical management of the patient (e.g. monthly CT Scans for conditions usually requiring a scan every three months)
- Items and services customarily provided by research sponsors free of charge for any enrollee in the trial
Seven 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.
Effective September 19, 2000, clinical trials that are “deemed” to be automatically qualified (i.e. automatically meet the seven desirable characteristics) 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, CMS, 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).
21 CFR 312.2 on IND Exemptions

- Must meet all five criteria
  - Study is not intended to support FDA approval of a new indication or a significant change in the product labeling.
  - The study is not intended to support a significant change in the advertising for the product.
  - The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
  - The study is conducted in compliance with institutional review board (IRB) and informed consent regulations.
  - The study is conducted in compliance with 312.7 (promotion and charging for investigational drugs).
The CTP does not withdraw coverage from IDE Category B trials, but there have been reports of Medicare contractors denying these trials because the support for “therapeutic intent” was insufficient.

The Second Consideration of the Clinical Trial Policy in 2007 (that was not implemented) included the following statements:

- “This policy is not applicable to, and does not change Medicare coverage according to the regulations on category A and category B investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406.”
- “Since humanitarian use devices (HUDs) with an FDA approved humanitarian device exemption (HDE) are not addressed in this policy, local contractors may continue to make determinations about the coverage of HUDs.”
Research Billing 101
Billing and Coding Definitions for the Non-Biller

- **UB-04 (Form CMS-1450)** - Standard paper claim form used by institutional providers, such as hospitals, to bill Medicare and various other third party payers. (The electronic version is referred to as the 837I.)
  

- **CMS 1500** - Standard paper claim form used by healthcare professionals (e.g. physicians) and suppliers (e.g. reference laboratories) to bill Medicare and various other third party payers. (The electronic version is referred to as the 837P.)
  
ICD-9-CM Diagnosis Code - The International Classification of Diseases, Ninth Revision, Clinical Modification that is currently used to report diagnostic information on claims. ICD-10-CM (tenth version) will replace ICD-9-CM in the future.

CPT/HCPCS Code - Codes that represent procedures, products, or services that may be provided to Medicare beneficiaries and to individuals enrolled in private health insurance programs.
Modifier - Provides the means by which the reporting physician or provider can indicate that a service or procedure performed has been altered or modified by a specific circumstance, but not changed in its definition or code.

- Only reported on outpatient or physician claims
- Proper use of modifiers is essential for submitting correct claims
- Certain modifiers are used by Medicare and other third party payers for payment purposes, whereas others are used for reporting and data collection purposes only
  - Q0 and Q1 are examples of modifiers used by Medicare only for data collection purposes and at this time do not result in payment decisions
    - Q0 Modifier – Investigational item/service, e.g. Investigational drug J9999Q0
    - Q1 Modifier – Routine item/service, e.g. Physical Exam 99215Q1
Research Billing 101
Billing and Coding Definitions for the Non-Biller

- **Revenue Code** - A four digit code that is submitted by institutional providers and represents a specific location or type of service provided
  - Payer billing requirements for revenue codes may vary
    - Example: Medicare accepts revenue code 0624 for IDEs, but many other payers allow for this to be billed using revenue code 0278, Other Implants

- **Condition Code** - Code reported in UB-04 fields 18-28 to describe any conditions or events that apply to the billing period, e.g. Condition Code 30, Qualifying Clinical Trial

- **Value Code** - A two digit or alphanumeric code that is reported in UB-04 fields 39-41 and is used to report additional information that applies to the billing period
  - D4 is reported when the clinical trial number assigned by the National Library of Medicine (NLM)/National Institutes of Health (NIH) is reported on the claim. Refer to other third party payer-specific policies for reporting requirements
**Charge Description Master (CDM)** - a comprehensive listing of items billable to a hospital patient or a patient's health insurance provider

- CDM includes, but is not limited to, the following items: CPT/HCPCS Code, Revenue Code, and price
- CDM may include certain modifiers (e.g. Q0 associated with an IDE)
- Certain institutions have a Research CDM specific to procedures, products, or services provided to clinical trial participants
UB-04 (CMS Form 1450)

Electronic version is 837I
### CMS Form 1500

**Electronic version is 837P**
### Research Billing 101
Billing and Coding Definition Examples

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<th>Item/Service</th>
<th>Coding Description</th>
<th>Includes</th>
<th>CPT/HCPCS</th>
<th>Revenue Code</th>
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<tbody>
<tr>
<td>Physical Exam</td>
<td>Evaluation &amp; Management</td>
<td>Medical History, Physical Vitals, Weight, BP</td>
<td>99201-99205; 99211 - 99215</td>
<td>510; Clinic</td>
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<tr>
<td>Chemistries</td>
<td>Basic Metabolic Panel (BMP)</td>
<td>BUN/Creatinine Ratio (calculated), Calcium, Carbon Dioxide, Chloride, Creatinine with GFR Estimated, Glucose, Potassium, Sodium, Urea Nitrogen (BUN)</td>
<td>80048</td>
<td>300; Laboratory 301; Chemistry</td>
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<td>Comprehensive Metabolic Panel (CMP)</td>
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<td>80053</td>
<td>300; Laboratory 301; Chemistry</td>
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# Research Billing 101

## Billing and Coding Definition Examples

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<tr>
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<td>Hematology</td>
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<td>Hematology</td>
<td>Complete Blood Count (CBC)</td>
<td>WBC, RBC, Hemoglobin, Hematocrit, MCV, MCH, MCHC, RDW, Platelet Count</td>
<td>85027</td>
<td>305; Hematology</td>
</tr>
<tr>
<td>Coagulation Studies</td>
<td>Prothrombin Time (PT)</td>
<td>INR- International Normalized Ratio</td>
<td>85610</td>
<td>305; Hematology</td>
</tr>
<tr>
<td>Coagulation Studies</td>
<td>Partial Thromboplastin Time, Activated aPTT</td>
<td></td>
<td>85730</td>
<td>305; Hematology</td>
</tr>
</tbody>
</table>
### Research Billing 101

**Billing and Coding Definition Examples**

<table>
<thead>
<tr>
<th>Item/Service</th>
<th>Coding Description</th>
<th>Includes</th>
<th>CPT/HCPCS</th>
<th>Revenue Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDG-PET Scan</td>
<td>PET whole body</td>
<td>Concurrent CT for attenuation correction and anatomical correction</td>
<td>78816</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDG, diagnostic, per study dose</td>
<td>Up to 45 millicuries</td>
<td></td>
<td>A9552</td>
<td></td>
</tr>
<tr>
<td>Device</td>
<td>Cardioverter Defibrillator, Dual Chamber (Implantable)</td>
<td>Prodigy® DR Legacy® DR</td>
<td>C1721</td>
<td>624- IDE (MCR) 278- Other Implants</td>
</tr>
<tr>
<td>Drug; Anti-Emetic</td>
<td>Ondansetron HCL Injection</td>
<td>Per 1 mg</td>
<td>J2405</td>
<td>636- Detailed drug coding</td>
</tr>
<tr>
<td></td>
<td>Ondansetron, Oral</td>
<td>Per 1 mg</td>
<td>Q0162</td>
<td>636- Detailed drug coding</td>
</tr>
</tbody>
</table>
# Research Billing 101

Billing and Coding Definition Examples

<table>
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<th>Revenue Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Administration</td>
<td>Chemo Infusion</td>
<td>Initial Hour; Additional Hour; Each Additional Drug</td>
<td>96413 96415 96417</td>
<td>335- Chemo Admin, IV</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non-Chemo Infusion</td>
<td>Initial IV Therapy; Each Additional Hour</td>
<td>96365 96366</td>
<td>260- IV Therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Injection</td>
<td>Subcutaneous/ intramuscular; Intra-arterial Intravenous push</td>
<td>96372 96373 96374-96736</td>
<td>331- Chemo Admin, Injection</td>
</tr>
</tbody>
</table>
## Research Billing 101
Medicare Claims Processing Manual, Chapter 32

<table>
<thead>
<tr>
<th>Item</th>
<th>Medicare Requirement(s)</th>
</tr>
</thead>
</table>
| **Routine Costs submitted by Physicians on CMS 1500**                | • ICD-9 Diagnosis code V70.7 – Examination of participant in clinical trial reported as a secondary  
  • ICD-10-CM Diagnosis code Z00.6 – Examination for normal comparison and control in clinical research program  
  • CPT Code Modifier (outpatient claims only)  
  • Q0 Modifier – Investigational clinical service  
  • Q1 Modifier – Routine clinical service                                                                                                                                                                                                                                                                                           |
| **Routine Costs submitted by Institutions**                         | • All of the above  
  • Condition Code 30 – Qualifying clinical trial  
  • Revenue Code 0624 – FDA Investigational Devices  
  • Reported on all outpatient claims even if the device is provided free of charge. If provided at no cost, must report a token charge (e.g. $1.00 or $00.01) in the non-covered charge field  
  • Reported only on inpatient claims if the device is not provided free of charge                                                                                                                                                                                                                                                   |
## Research Billing 101
Medicare Claims Processing Manual, Chapter 32

<table>
<thead>
<tr>
<th>Item</th>
<th>Medicare Requirement(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Records</td>
<td>Must include:</td>
</tr>
<tr>
<td></td>
<td>• Trial Name</td>
</tr>
<tr>
<td></td>
<td>• Trial Sponsor</td>
</tr>
<tr>
<td></td>
<td>• Sponsor-Assigned Protocol Number</td>
</tr>
<tr>
<td>Registry Number</td>
<td>• 8-digit National Clinical Trial (NCT) identifier number is required as of January 1, 2014 (and Value Code D4 on an institutional claim only)</td>
</tr>
<tr>
<td></td>
<td>• Exceptions- Studies that have been approved through the Coverage with Evidence Development (CED) may require this for coverage and payment purposes</td>
</tr>
<tr>
<td>Device Trials</td>
<td>• IDE number assigned by the FDA</td>
</tr>
<tr>
<td></td>
<td>• Reported in field 43 on a UB-04</td>
</tr>
<tr>
<td></td>
<td>• Reported in item 23 on a 1500 claim form</td>
</tr>
<tr>
<td></td>
<td>• Modifier FB and FC to identify CPT/HCPCS procedure code when certain IDEs are provided free of charge or at a reduced cost as part of a device study</td>
</tr>
</tbody>
</table>
Qualifying Clinical Trial

**Medicare Clinical Trial Policy**

- Instructions apply to conventional care, including treatment of complications
- Billing provider must include in the medical record the following information: trial name, trial sponsor, and sponsor-assigned protocol number

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>Hospital Charges (UB-04)</th>
<th>Professional Charges (CMS-1500)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inpatient Claims</strong></td>
<td><strong>Outpatient Claims</strong></td>
<td><strong>Professional Charges</strong></td>
</tr>
<tr>
<td><strong>Qualifying Clinical Trial</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medicare Clinical Trial Policy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ICD-9 diagnosis code V70.7 as the second diagnosis code for trial participation</td>
<td>- ICD-9 diagnosis code V70.7 as the primary diagnosis code for healthy controls only</td>
<td></td>
</tr>
<tr>
<td>- ICD-9 diagnosis code V70.7 as the primary diagnosis code for healthy controls only</td>
<td>- Q1 Modifier for both participants and healthy controls - apply to each service identified as conventional care only on line items related to the clinical trial</td>
<td></td>
</tr>
<tr>
<td>- Condition Code 30 (qualifying clinical trial) reported at the claim level for both trial participants and healthy controls</td>
<td>- Q0 Modifier for each service identified as investigational</td>
<td></td>
</tr>
<tr>
<td>- Include V70.7 and Condition Code 30 regardless of whether all services on the claim are related to the clinical trial or not</td>
<td>- Condition Code 30 (qualifying clinical trial) reported at the claim level for both trial participants and healthy controls</td>
<td></td>
</tr>
<tr>
<td>- NCT # required as of January 1, 2014</td>
<td>- Include V70.7 and Condition Code 30 regardless of whether all services on the claim are related to the clinical trial or not</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- NCT # required as of January 1, 2014</td>
<td></td>
</tr>
</tbody>
</table>

Note: CMS will return claims as unable to process if the V70.7 is not on claim with the Condition Code 30.

- NCT # preceded by “CT” required as of January 1, 2014
CMS will make payments for Medicare Managed Care or Advantage Plan (MA) enrollees on a fee-for-service basis for covered clinical trial costs under the September 2000 NCD. This policy is in effect until further notice.

The MA enrollees are liable for the coinsurance amounts applicable to services paid under the Medicare fee-for-service rules, but are not responsible for the deductibles.

Clinical trial coding requirements are the same as for regular Medicare fee-for-service claims.

- Institutional providers **cannot** bill outpatient clinical trial-related and nonclinical trial-related services on the same claim. Provider must split bill, with nonclinical trial-related services being billed to the MA Plan (MAP).

Category B IDE studies are covered by the MAPs (with CMS’s rules and guidelines) since November 1, 1995. Costs are included in the MA payment rates.
For potential Medicare coverage associated with items and services provided as part of a device study, NSLIJ must submit the protocol and other associated documents to NGS, your local Medicare contractor to determine coverage for the following device studies if billing for routine costs until 1/1/15 when this will be centralized at CMS per 2014 Final Rule:

- IDE Category B Devices assigned by the FDA with a number beginning with a “G”
- IDE Category A Devices
- PMA studies or registries of carotid stents
- Studies for proximal Embolic Protection Device (EPD) in Carotid Artery Stenting (CAS) procedures

Documents may include, but are not limited, to the following:

- Name and Narrative Description of Device
- Study Protocol
- Informed Consent Form
- Un-redacted/Unconditional FDA Approval Letter
- IRB Approval Letter
Medicare contractors apply the following criteria when determining coverage for a FDA-approved IDE Category B device:

- The device must be used within the context of the FDA-approved clinical trial;
- The device must be used according to the clinical trial’s approved patient protocols;
- There may be an established national policy as contained in existing manual instructions, e.g., National Coverage Determinations Manual instructions, etc.;
- In the absence of national policy, there may be a local policy for similar FDA-approved devices;
- There may be Policy/Position papers or recommendations made by pertinent national and/or local specialty societies.

Contractors should also consider, among other factors, whether the device is:

- Medically necessary for the particular patient and whether the amount, duration, and frequency of use or application of the service are medically appropriate; and
- Furnished in a setting appropriate to the patient’s medical needs and condition.
Per Mandatory Reporting of Clinical Trial Identifier Numbers on Medicare Claims- Qs & As, 5/16/14

- Medicare will reimburse qualifying clinical trials on behalf of MA members and will waive the Part A and the part B deductibles. MA plans are responsible for the remaining original Medicare coinsurance minus the plan’s normal member copays.
- The NCT identifier must be reported on the claim to Medicare when the patient is receiving treatment during a qualifying clinical trial, has finished active treatment and is being seen yearly for observation and if the patient is in an observation-only trial.
- If a physician orders labs dictated by the study and also orders additional labs, the -Q1 modifier is put on the study-dictated labs, but not on the additional labs.
- Only those services that are part of the clinical trial, including routine care for the condition of the clinical trial, need to be submitted with an NCT identifier number on a Medicare Claims related to the clinical trial. Providers are expected to use their professional judgment in determining items/services related to the trial.
Research Billing 101

Resources

- JK: The Qualifying Clinical Trial- Medicare Billing Guidelines, July 2014
  - [http://www.NGSMedicare.com](http://www.NGSMedicare.com), Select Jurisdiction K Part A, Training Events Calendar, Attachments for this Event


- Mandatory Reporting of Clinical Trial Identifier Numbers on Medicare Claims-Qs & As

- Claims Processing Manual 104, Chapter 32, Section 67-69: No Cost Claims, Investigational Device Exemption, Qualifying Clinical Trials
  - [https://www.cms.gov/manuals/downloads/clm104c32.pdf](https://www.cms.gov/manuals/downloads/clm104c32.pdf)
Research Billing 101
Resources

- CMS Transmittal on New HCPCS Modifiers When Billing for Patient Care in Clinical Research Studies

- CMS Guidance is found in the Benefit Policy Manual (BPM) Chapter 14: Medical Devices

- 42 CFR 405.209 – Payment for a Non-Experimental/Investigational (Category B) Device

- Clinical trials website:
  - http://www.clinicaltrials.gov
Break
Q & A