PREP Course #24: Clinical Research Billing with Patient Financial Services

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CME Disclosure Statement

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• Course Director and Course Planner, Kevin Tracey, MD and Tina Chuck, MPH have nothing to disclose.

• Sumathy Sundarababu has nothing to disclose
Objectives

- Clinical Research Billing background
- Overview of Billing processes
- Research billing and the role of patient financial services
- Billing Outpatient and Inpatient services in clinical trials
- New requirements for IDE device billing
- Medicare Managed Care billing (MAP)
Clinical Research Billing with Patient Financial Services

Clinical Trials
- Types of Clinical Trials
- Types of Device Trials

Clinical Trial Billing
- Billing and Coding Definitions
- Common Study-Related Items / Services Codes
- Medicare Claims Processing Manual, Chapter 32
- Medicare Advantage (MA) Patients

Case Studies – Medicare Billing and Coding
- IV Drug Study
- Cardiac Device Study
Different Types of Clinical Trials
Trials may be conducted for various purposes:

- **Treatment Trials** test experimental drugs/treatments, new combination of drugs, or new approaches to surgery or radiation treatment
  - **Example:** Testing new drugs in Breast cancer

- **Prevention Trials** seek better ways to prevent disease in people who have never had the disease, or to prevent a disease from returning
  - **Example:** Studying a food supplement to see how useful it is at lowering cancer risk

- **Diagnostic Trials** are conducted to find better means of diagnosing a disease or condition
  - **Example:** New imaging methods to find cancer

- **Screening Trials** test the best way to detect certain disease or health conditions
  - **Example:** Genetic tests to detect inherited gene mutations associated with cancer

- **Quality of Life Trials** explore ways to improve quality of life for those with chronic illness
  - **Example:** Where quality of life measures are used in population surveys
Treatment Trials

Drug Trials:

• IND

• IND Exempt

Device Trials:

• Investigational Devices: Category A or B

• FDA approved devices: Post market studies

Other: Surgery
Investigational Devices: Category A & B IDEs

The FDA assigns a special identifier number that corresponds to each device granted an IDE. For purposes of assisting the Centers of Medicare & Medicaid Services (CMS) in determining Medicare coverage of items and services in IDE studies, the FDA places all approved IDE devices in one of two categories:

<table>
<thead>
<tr>
<th>Category A</th>
<th>Category B</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Experimental device</td>
<td>• Non-experimental device</td>
</tr>
<tr>
<td>• There is an “absolute risk” of the device type has not been established</td>
<td>• Incremental risk is the primary risk in question</td>
</tr>
<tr>
<td>• Device never covered by Medicare</td>
<td>• May be covered by Medicare</td>
</tr>
<tr>
<td>• Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met</td>
<td>• Medicare may make payment for a Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE study.</td>
</tr>
</tbody>
</table>

IDE #number begins with a “G”
Research Billing
Overview &
Best practices
Why is Medicare important?

• Largest Single payer

• Drives reimbursement rules in United states

• Federal payer

• Aims for the “Best Deal”

• Many commercial health plans have adopted Medicare CTP rules

• Impractical to perform coverage analysis for all commercial payers
Clinical Trial Policy (CTP) NCD 310.1

“. . . 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.”

Source: Clinical Trial Policy
What is billable in clinical trials? Routine costs

• Routine costs: items/services typically provided for direct patient care absent a clinical trial (i.e. conventional care)

• Items/services required for the provision of the investigational item or service, the clinically appropriate monitoring/prevention of the effects of the item/service

• Items/services required for the prevention, diagnosis, or treatment of research related adverse events.
What are not billable in clinical trials?

• Investigational item itself

• Items provided free of cost or paid by sponsor

• Items where no medicare benefit category exist (tummy tuck, breast implant etc)

• Items provided only to determine trial eligibility

• Items/services provided only to satisfy data collection
(To determine qualifying clinical trial and what can be billed to insurance)

Medicare coverage analysis
or
Coverage analysis
or
Cost analysis
or
Billing grid
This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity.

### Initial Therapy (RVD Cycle 1)

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Screening</th>
<th>Treatment days</th>
<th>NCD/LCD/Other supporting documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£ 21 days from initiation of protocol therapy</td>
<td>Baseline Day 1, Day 4, Day 8, Day 11</td>
<td></td>
</tr>
</tbody>
</table>

### Informed consent

<table>
<thead>
<tr>
<th>NA</th>
<th>R</th>
<th>paid by study</th>
</tr>
</thead>
</table>

### Physical examination, ECOG

<table>
<thead>
<tr>
<th>99211-99213</th>
<th>R</th>
<th>SOC</th>
<th>Screening visit paid by study. Baseline visit (NCD70.3; NCCN guidelines [<a href="http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf">http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf</a>]; NCD 310.1 reasonable &amp; necessary for the clinical management of patient/evaluation &amp; administration of drug/service)</th>
</tr>
</thead>
</table>

### FACT/GOG NTx questionnaire

<table>
<thead>
<tr>
<th>NA</th>
<th>NB</th>
<th>Non billable. Completed by patient</th>
</tr>
</thead>
</table>

### Skeletal survey (CT or MRI as clinically indicated)

<table>
<thead>
<tr>
<th>78306;78811</th>
<th>R</th>
<th>SOC</th>
<th>Screening imaging paid by study. Baseline scan ([<a href="http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf">http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf</a>]; NCD 310.1 reasonable &amp; necessary for clinical management of patients); To evaluate bone disease (NCD 150.3) and to evaluate active myeloma (PET CT NCD 220.6)</th>
</tr>
</thead>
</table>

### Hematology

<table>
<thead>
<tr>
<th>85025</th>
<th>SOC</th>
<th>SOC</th>
<th>SOC</th>
<th>SOC</th>
<th>SOC</th>
<th>Bortezomib &amp; Revlimid toxicities include thrombocytopenia/neutropenia. Therefore monitoring/prevention of complications is covered (NCD 310.1)</th>
</tr>
</thead>
</table>

### Study drugs administration

<table>
<thead>
<tr>
<th>Bortezomib J9041; IV 96413</th>
<th>SOC</th>
<th>NCD 310.1 (administration of investigational item/service)</th>
</tr>
</thead>
</table>

R research billed to study; SOC Standard of care billed to insurance; NB Not billable

For Billers: On outpatient insurance claims capture v70.7 cc30 and Q1 HCPCS modifier; On inpatient claims capture v70.7, cc30 only
Things to know before you bill…….

• How many insurance payers the subject has?

• if Commercial payer: Obtain Pre-authorization

• For Medicare: Obtain CMS coverage approval letter for IDE studies from Sponsor

• Ensure a Coverage analysis /billing grid in place
PRE-AUTHORIZATION
Clinical Trial Commercial Payer Authorization Checklist

 Cover letter

 Protocol Synopsis

 IRB approval letter

 IRB approved consent, signed by patient

 Items that the trial will/will not cover (from MCA)

 IND/IDE/IND exemption info

 Medical records

 Any other reference materials
Sample Cover letter to Commercial Insurance Company for Coverage of Clinical Trials

(Name of Contact Person at Insurance Company) (Insurance Company's Name)  
(Address) (City, State, Zip Code)

Re: (Patient's Name)  
{Date of Birth}  
(Patient's Insurance 10 Number)

Dear (Name of Contact Person at Insurance Company- Utilization Management Medical Director), (Insert patient's name) has been under my care since (insert date) for evaluation and treatment of (insert condition), which is a life threatening condition left untreated. (Give brief medical history emphasizing the most recent events that led to consideration of enrolling patient into the clinical trial).

(Insert patient's name) meets eligibility criteria for the (Insert name of clinical trial). The (Insert name of clinical trial) clinical trial's main objective are to: {list main objectives).

Further, (Insert patient's name) participation in the (Insert Clinical Trial Name) meet all criteria for health plan coverage as indicated by the Affordable Care Act which requires health plans to cover routine patient costs incurred by qualified individuals who are participating in an approved clinical trial (QCT). Specifically, the aforementioned criteria is met by the following:

• (Insert patient's name) is covered for treatment of this condition under the plan's benefits.  
• (Insert patient's name) meets eligibility criteria for this clinical trial.  
• (Insert Clinical Trial Name) Is an QCT because {list reason(s) the trial meets QCT criteria, for example):
  o (Insert Phase I, Phase II, Phase Ill or Phase IV clinical trial).
  o (The trial is being conducted in relation to the prevention, detection or treatment for cancer or other life threatening disease or condition).
  o (The trial is federally funded and/or conducted under on Investigational New Drug {INO} application review by the Food and Drug Administration {FDA) or IND exemption)

I have included in the packet attached to this letter including a Clinical Trial Authorization Request Form and the following information: (list all// Information attached)

I ask that you consider authorizing (Insert patient's name) participation and coverage in the above-mentioned clinical trial including coverage of all associated routine care items and services. I would like to enroll her/him into the clinical trial by (insert date). Should you have any questions, please call me at (insert phone number).

Sincerely,

(Doctor's Name)
Obtain Pre-Authorization (Non-Medicare)

**Patient consented and qualifies for enrollment in the trial**

* Preauthorization request submitted to payer

**Call payer to verify benefits and confirm contact person for preauthorization**

**Authorization received**

- Yes
  - Record preauthorization number, scope of the service(s) authorized, code(s) recommended, the date and time and name of person authorizing the services in the patient's file

- No
  - *Determine why request denied.*

**Appeal process**

* Letter should include:
  - Statement of Medical necessity
  - Details on why this procedure is preferred over other treatments
  - CPT codes
  - FDA status
CLAIM FORMS & CODING
Institutional/Hospital/Technical Billing Form UB-04

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
Billing and Coding Definitions

**ICD-10-CM Diagnosis Code** - The International Classification of Diseases, Tenth Revision, Clinical Modification that is currently used to report diagnostic information on claims.

**Clinical trial subjects**: Actual diagnosis in primary position

Zoo.6 (ICD 10 CM code for examination of participants in clinical trial) secondary

**CPT/HCPCS Code** - Codes that represent procedures, products, or services that may be provided to Medicare beneficiaries and to individuals enrolled in private insurance.

Examples:

- ECG 93000
- CBC 85025
- Fluoroscopic guidance needle placement 77002
MODIFIERS ON CLAIM FORMS

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.

Clinical Trial modifiers
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 J9999 Q0
Q1 Modifier – Routine item/service, e.g. Physical Exam 99211 Q1
OTHER CODES ON CLAIM FORMS

Revenue Code – A code that is submitted by institutional providers and represents 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, CC 53, 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
FD is reported by institutional providers to indicate the cost reduction or cost of certain devices provided free of charge
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
# Common Study Items / Services - Billing and Coding

<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><strong>Physical Exam</strong></td>
<td>Evaluation &amp; Management</td>
<td>Medical History, Physical Vitals, Weight, BP</td>
<td>99201 - 99205; 99211 - 99215</td>
<td>510; Clinic</td>
</tr>
<tr>
<td><strong>Chemistries</strong></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>
</tr>
<tr>
<td><strong>Comprehensive Metabolic Panel (CMP)</strong></td>
<td>BMP plus Albumin, Albumin/Globulin Ratio (calculated), Alkaline Phosphatase, ALT, AST, Total Bilirubin, Total Protein</td>
<td></td>
<td>80053</td>
<td>300; Laboratory 301; Chemistry</td>
</tr>
<tr>
<td>Item/Service</td>
<td>Coding Description</td>
<td>Includes</td>
<td>CPT/HCPCS</td>
<td>Revenue Code</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------------</td>
<td>-----------</td>
<td>-----------</td>
<td>------------------------------</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></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chemo Infusion</td>
<td>Initial Hour;</td>
<td>96413</td>
<td>335; Chemo Admin, IV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional Hour;</td>
<td>96415</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Each Additional Drug</td>
<td>96417</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non-Chemo Infusion</td>
<td>Initial IV Therapy;</td>
<td>96365</td>
<td>260; IV Therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Each Additional Hour</td>
<td>96366</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Injection</td>
<td>Subcutaneous/ intramuscular;</td>
<td>96372</td>
<td>331; Chemo Admin, Injection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intra-arterial Intravenous push</td>
<td>96373</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>96374 - 96736</td>
<td></td>
</tr>
</tbody>
</table>
### 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>Claims must include Registry</td>
<td>• 8-digit National Clinical Trial (NCT) identifier number is required as of January 1,</td>
</tr>
<tr>
<td>Number</td>
<td>2014.</td>
</tr>
<tr>
<td></td>
<td>• Studies that have been approved through the Coverage with Evidence Development (CED)</td>
</tr>
<tr>
<td></td>
<td>may require this for coverage and payment purposes</td>
</tr>
</tbody>
</table>
CLINICAL TRIAL CLAIMS
Medicare Claims Processing Manual, Chapter 32

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>Hospital Charges (UB-04)</th>
<th>Hospital Charges (UB-04)</th>
<th>Professional Charges (CMS-1500)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inpatient Claims</td>
<td>Outpatient Claims</td>
<td></td>
</tr>
<tr>
<td>Qualifying Clinical Trial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare Clinical Trial Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Instructions apply to conventional care, including treatment of complications</td>
<td>• ICD-10 diagnosis code Z00.6 secondary diagnosis code for trial participation</td>
<td>• ICD-9 diagnosis code Z00.6 as the secondary diagnosis code</td>
<td>• ICD-9 diagnosis code Z00.6 as the secondary diagnosis code</td>
</tr>
<tr>
<td></td>
<td></td>
<td></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>• Q1 Modifier- apply to each service identified as conventional care only on line items related to the clinical trial</td>
<td>• Q1 Modifier- apply to each service identified as conventional care only</td>
<td>• Q1 Modifier- apply to each service identified as conventional care only</td>
</tr>
<tr>
<td></td>
<td>• NCT#</td>
<td>• NCT#</td>
<td>• NCT#</td>
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<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
### Item Medicare Requirement(s) Outpatient claims-IDE

<table>
<thead>
<tr>
<th>Routine Costs submitted by Physicians on CMS 1500</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>ICD-10-CM Diagnosis code Z00.6</strong> – Examination of participant or control in clinical research program</td>
</tr>
<tr>
<td>• CPT Code Modifier (outpatient claims only)</td>
</tr>
<tr>
<td>• <strong>Q0 Modifier</strong> – Investigational clinical service</td>
</tr>
<tr>
<td>• <strong>Q1 Modifier</strong> – Routine clinical service</td>
</tr>
<tr>
<td>• <strong>NCT#</strong> on medicare claims</td>
</tr>
<tr>
<td>• <strong>IDES#</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Routine Costs submitted by Institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>UB-04</strong></td>
</tr>
<tr>
<td>• <strong>CMS 1450</strong></td>
</tr>
<tr>
<td>• <strong>All of the above</strong></td>
</tr>
<tr>
<td>• <strong>Condition Code 30</strong> – Qualifying clinical trial</td>
</tr>
<tr>
<td>• <strong>IDE Devices</strong>: on Revenue Code 0624 line – capture device HCPCS codes, HCPCS modifiers (Q1/Q0), category B IDE#.</td>
</tr>
<tr>
<td>• value code FD with the $ amt/ $ 0 (no cost device) for the devices with Condition code 53 (initial placement of medical device part of clinical trial or free sample)</td>
</tr>
<tr>
<td>• <strong>NCT#</strong> on Medicare claims</td>
</tr>
</tbody>
</table>
Case Studies – Medicare Billing and Coding Guidance
IV Drug Case Study

Is the CBC & Infusion billable to Medicare?

CBC
CPT Codes: 85025-85027

“This test is done on the first week of each treatment cycle for the clinical management of the patient and to detect, monitor, and treat potential side effects of the study medication” (Protocol)

“The study drug and the accompanying regimen of chemotherapy drugs are known to cause hematological toxicities” (ICF)

“Sponsor agrees to reimburse Institution for blood panels that are not standard of care and are required by the Protocol” (Budget)

1. Support for Medicare Coverage
2. Identification of Limitations on State Local Coverage Determination (LCD) or National Coverage Determination (NCD)
3. Conventional Care Reference (As appropriate)

NCD 190.15
“Indications for hemogram or CBC related to red cell (RBC) parameters of the hemogram include signs, symptoms, test results, illness, or disease that can be associated with anemia or other red blood cell disorder.”

NCD 310.1
“Clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.”

YES, this service is covered and billable to Medicare

Related information found in relevant documents
**IV Drug Case Study**

Cycle 1 Week 1 - Billing Designations

-A Coverage Analysis should be done for each item (Z00.6 ICD 10 code in secondary; Condition code 30; appropriate revenue codes)

<table>
<thead>
<tr>
<th>Item</th>
<th>Designation</th>
<th>Q1</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC</td>
<td>S</td>
<td>Billable to Patient/Insurance</td>
</tr>
<tr>
<td>Venipuncture</td>
<td>S</td>
<td>Billable to Patient/Insurance</td>
</tr>
<tr>
<td>Bendamustine</td>
<td>S</td>
<td>Billable to Patient/Insurance</td>
</tr>
<tr>
<td>Study drug XYZ</td>
<td>Non Billable. Provided free of cost</td>
<td></td>
</tr>
<tr>
<td>IV Administration</td>
<td>S</td>
<td>Billable to Patient/Insurance</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>R</td>
<td>Research/Paid for by Sponsor</td>
</tr>
</tbody>
</table>

CBC, Venipuncture, Bendamustine and IV Administration are billable to Medicare
Value Code ‘D4’ and 8-digit NCT identifier number in Box 39

Modifier Q1 or Q0 in Box 44

Condition Code ’30’ in Box 18

ICD-9 code V70.7 / ICD-10 code Z00.6 in the secondary position in Box 66

36415 = Venipuncture
85025 = CBC
96413 = Chemotherapy Infusion, Up to 1 Hour
96415 = Chemotherapy Infusion, Each Additional Hour
J9033 = Bendamustine, 180 Mg (Drug)

204.10 = Chronic lymphoid leukemia
CMS Form 1500 – Clinical Trial Identifiers

8-digit NCT identifier number in Box 19 with “CT” attached. Electronic version 837P does not require “CT”

ICD-9 code V70.7 / ICD-10 code Z00.6 in the secondary position in Box 21

204.10 = Chronic lymphoid leukemia

Modifier Q1 or Q0 in Box 24.D

36415 = Venipuncture
85025 = CBC
CARDIAC DEVICE- CASE STUDY

Investigational Item: HIL STENT™ System

Device IDE: G12345

Device Category: B

On the Implant Procedure day, the protocol requires a:

- Percutaneous Coronary Intervention (PCI)
- Anesthesia
- Transthoracic Echocardiography (TTE) and
- Study Device Stent HIL™ System

What items and services for the procedure are billable to the insurance (Medicare) or sponsor?
Implant Procedure Day - Billing Designations

A Coverage Analysis should be done for each item

- HIL STENT™ System is billable to the sponsor

-PCI, Anesthesia and TTE is billable to Medicare

-NOTE: NGS has an LCD (L27360) for the TTE
CARDIAC DEVICE STUDY
UB-04 Example – Clinical Trial Identifiers

Condition Code ‘30’ in Box 18
Condition Code “53” after 7/1/2015
Value Code ‘D4’ and 8-digit NCT identifier number in Box 39
Value Code ‘FD’ when certain IDEs are provided free of charge
Revenue Code 624 with token charge (e.g. 1.00) in Box 42
IDE number assigned by the FDA in Box 43
Modifier Q1 or Q0 in Box 44

92920 = PCI
00562 = Anesthesia
93000 = Transthoracic Echocardiography
C9899 = Investigational Device

NGS has an LCD (L27360) for the TTE. Review to determine if primary diagnosis code for trial participant supports coverage by Medicare.
CARDIAC DEVICE STUDY

CMS Form 1500 – Clinical Trial Identifiers

8-digit NCT identifier number in Box 19 with “CT” attached. Electronic version 837P does not require “CT”

ICD-9 code V70.7 / ICD-10 code Z00.6 in the secondary position in Box 21

NGS has an LCD (L27360) for the TTE. Review to determine if primary diagnosis code for trial participant supports coverage by Medicare.

Modifier Q1 or Q0 in Box 24.D

93303 = Transthoracic Echocardiography
MEDICARE ADVANTAGE PLAN (MAP)
What is Medicare Advantage?

Medicare Advantage is an optional program for seniors that provides the same benefits as Medicare Part A (inpatient insurance) & Part B (outpatient and physician insurance).

• CMS contracts with private insurance companies to administer Medicare Advantage benefits; these are referred to as Medicare Advantage Plans (MAPs)

• Medicare Advantage is “Part C” of Title XVIII of the Social Security Act
• Medicare Advantage is formerly known as:
  • Medicare + Choice
  • Medicare Managed Care
“[F]or beneficiaries enrolled in a managed care plan, institutional providers must not bill outpatient clinical trial services and nonclinical trial services on the same claims. If covered outpatient services unrelated to the clinical trial are rendered during the same day/stay, the provider must split-bill so that ONLY the clinical trial services are contained on a single claim and billed as fee-for service...Any outpatient services unrelated to the clinical trial should be billed to the managed care plan.”
Billing Clinical Trial (Drug trial) SOC services for patients with Medicare Advantage plan:

**Standard of care (SOC) charges**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Qualifying Drug Trials</th>
<th>IDE Device Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outpatient (split bill)</strong></td>
<td>Clinical trial charges to Medicare; Charges unrelated to clinical trial bill MAP</td>
<td>Clinical trial charges to MAP</td>
</tr>
<tr>
<td><strong>Inpatient</strong></td>
<td>Clinical trial charges to Medicare as primary and MAP secondary</td>
<td>Clinical trial charges to MAP (primary)</td>
</tr>
</tbody>
</table>

For MAP Denials: Address the guidelines with them and MAP will pay.
Which services are billed to Original Medicare in qualifying drug trials?

• **Follow the MCA**

  • If the service is on the MCA (part of study schedule of assessments), then the service should be billed to Original Medicare
    Example: protocol scheduled ECG.

  • If the service has nothing to do with the study and is not scheduled by the protocol, then bill to the MAP
    Example: patient has tooth pain requires root canal.

  • If the service is to treat a complication related to the investigational item, then the service should be billed to Original Medicare
MAP BILLING (Drug trials)

TAKE HOME MESSAGE:

- Hospital outpatient setting: Encounters including research-related services - potential split-billing

- Inpatient care: CMS is not clear on the impact for split-billing. An inpatient claim cannot be “split.”

Options:
If the reason the patient is admitted is unrelated to the study, then send claim to MAP
- Keep “routine cost” charges off the UB claim form for MAP patients or place in non covered column
- Pre-authorize with MAP
- Use Z00.6 code

If no automated process, then hold MAP research subject claims for manual review.
Questions?
THANK YOU

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