Clinical Trial Billing

Presented by:
Clinical Trial Steering Committee
Agenda

- Jefferson Clinical Research Institute’s (JCRI) Role and the Coverage Analysis
- Clinical Trial Compliance
- Clinical Trial Operational Process
- Coding & Billing
- Discussion
JCRI’s Role and The Coverage Analysis
Pre-award Process

- Receives documents from Study Team:
  - Protocol
  - Draft Informed Consent (ICF)
  - Clinical Trial Agreement (CTA)
  - Sponsor Budget

- JCRI creates Electronic Proposal Transmittal Form (ePTF)

- Step 1:
  - Create a Coverage Analysis (CA)
What is a Coverage Analysis?

• Document that determines the appropriate payor (i.e. Sponsor, Medicare or third party payor) for each item and service required by a clinical research trial
Why is a Coverage Analysis important?

• Reduces risk for submitting false claims
  • Billing for services not part of a qualifying clinical trial
  • Billing for items and services promised/paid for by Sponsor
  • Billing for research only items and services

• Assists in budget negotiations with Sponsor/CRO
  • Identifies costs that need to be accounted for in the sponsor budget

• Basis of billing compliance/audits
  • Provides evidence of due diligence and a mechanism for compliance with billing rules
Coverage Analysis Process

• Receive all materials from the study team

• Create a grid that reflects all clinical events and time points in the protocol

• Review clinical guidelines along with CMS national and local coverage determinations to identify the appropriate payor for each event

• Send the CA to PI/SC for review and approval

• Approve or revise the CA as necessary
### Time & Effort

<table>
<thead>
<tr>
<th>Items and Services</th>
<th>CPT/HCPCS Codes</th>
<th>Q1/Q0 Mod</th>
<th>Screening¹</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>N/A</td>
<td>No</td>
<td>S</td>
<td></td>
<td></td>
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<tr>
<td>Inclusion/Exclusion Criteria</td>
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<td>No</td>
<td>S</td>
<td></td>
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<tr>
<td>Medical History</td>
<td>N/A</td>
<td>No</td>
<td>S</td>
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<td></td>
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</tr>
<tr>
<td>Concomitant Medications</td>
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<td>No</td>
<td>S S S S S S</td>
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<td></td>
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<tr>
<td>Adverse Event Assessment</td>
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<td>No</td>
<td>S S S S S S</td>
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</tbody>
</table>

¹Screening performed once per cycle, at response assessments.

### Evaluation & Management Services

**Complete Physical Exam**

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
<th>Q1/Q0 Mod</th>
<th>Screening¹</th>
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<th>Cycle 2</th>
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<tbody>
<tr>
<td>99201 - 99205; 99211 - 99215 G0463</td>
<td>Q1</td>
<td>M M M</td>
<td>M</td>
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</table>

According to the NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma Version 2.2014 "NCCN Guidelines" a physical exam is considered conventional care at workup (NCCN Guidelines, p. 6). Patients in this trial have a confirmed diagnosis of relapsed/refractory multiple myeloma after treatment with at least two different previous regimens. Prior treatment must include at least two standard anti-myeloma therapies or induction therapy followed by autologous stem cell transplant (Protocol, p. 23). The study drug given in this trial has unknown side effects. A physical exam at screening, once per cycle and at response assessments appear reasonable and necessary for the clinical management of the patient in order to monitor disease progression and potential side effects. Coverage supported by NCD 310.1.

### Labs

**CBC with Differential**

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
<th>Q1/Q0 Mod</th>
<th>Screening¹</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>85025 or 85027 and 85007</td>
<td>Q1</td>
<td>M M M M M M M M</td>
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</tbody>
</table>

A CBC with differential is considered conventional care at initial workup (NCCN Guidelines, p. 6). The study drug, ALT-803, caused an increase in white blood cell counts in animal studies (Protocol, p. 18-19). Patients in this trial have multiple myeloma which also affects blood counts. CBC testing throughout treatment appears to be done both for the clinical management of the patient and to monitor, assess and treat for potential complications associated with the study drug. Coverage supported by NCD 310.1 and NCD 190.15.

### Scans/Procedures

**Electrocardiogram (EKG)**

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
<th>Q1/Q0 Mod</th>
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<tbody>
<tr>
<td>93000 - 93010</td>
<td>No</td>
<td>S S S S S S</td>
<td>S</td>
<td></td>
</tr>
</tbody>
</table>

The study drug does not appear to have cardiac side effects, and states that "no dose related abnormalities based on ECG or ophthalmic evaluations were

### Study Medications

**ALT-803 (IV)**

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
<th>Q1/Q0 Mod</th>
<th>Screening¹</th>
<th>Cycle 1</th>
<th>Cycle 2</th>
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<tbody>
<tr>
<td>J9999</td>
<td>Q0</td>
<td>NB NB NB NB</td>
<td>NB NB NB NB</td>
<td></td>
</tr>
</tbody>
</table>

The study drug will be provided by the sponsor. The protocol states: "ALT-803 is an investigational drug supplied to investigators by the Altor Bioscience Corporation at Miramar, Florida. Sufficient study drug will be available for this protocol to treat all of IV administration of the study drug is supported by NCD 310.1.

### Coverage Code Key

- **M**: Medicare or Other Health Plan
- **S**: Charged to Study Fund or Sponsor
- **NA**: Bundled With Another Payment From Third Party
- **NB**: Not Billed to Anyone, Not a Billed Event, No CPT Code
How Will This Process Change with JeffTrial & Epic?

• JCRI Business Operations will now create the coverage analysis within JeffTrial

• The JeffTrial calendar will link to Epic

• Once the coordinator links the patient to a clinical trial, the billing determinations will already be part of the calendar

• When the patient is checked-in as a part of a research visit, the services rendered as part of their visit will automatically pull from the billing determination in JeffTrial

• The subsequent claim will initially be sent to coders, in order to associate the correct code, then resent to JCRI Business Operations for a final review
Pre-Award Process

- Develop and negotiate budget
- Review and negotiate clinical trial agreement
- Execute agreement
- Input final budget into ePTF & route for approval
- Send for account establishment
- Share the approved MCA with:
  - PI/Coordinator/Department
  - JUP physician billing
  - TJUH Business services and billing
Clinical Trial Operational Workflow
Clinical Trial Operational Goals

- Ensure compliance with Federal, state, and local regulations
- Minimize patient billing errors and/or patient dissatisfaction
- Encourage participation in research activities through transparency and integrity
- Optimize cost recovery
- Minimize denials and/or claims processing errors
- Develop tools that are efficient and effective for charge segregation and claims review
High Level Operational Workflow

1. Identify (and consent) Potential Research Subjects
2. Complete Case Information Form
3. Link Clinical Services to a Case
4. Hospital Registration (JeffChart)
5. Coding / Billing Reconciliation
Clinical Trial Subjects

• Identify population based on the clinical diagnosis

• Provide patients with study information

• Obtain consent
Complete and Submit Case Information Form

- Critical step to ensuring correct and compliant Clinical Trial billing
**JEFFERSON UNIVERSITY PHYSICIANS CASE INFORMATION**

<table>
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<th>Information</th>
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<tr>
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<tr>
<td>Patients Name</td>
<td>Susan Stralost, DDS</td>
</tr>
<tr>
<td>Type of Case</td>
<td>Clinical Trial</td>
</tr>
<tr>
<td>Description of Clinical Trial</td>
<td>ECOG</td>
</tr>
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<td>Department Name</td>
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<td>Kimmel Cancer Center – CRMO - 490 Jeff Hall Philadelphia, Pa 19107</td>
</tr>
<tr>
<td>Study Coordinator Name</td>
<td>LouEllen Daniel</td>
</tr>
<tr>
<td>Study Coordinator Number</td>
<td>215-503-5390</td>
</tr>
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<tr>
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<td>Patient Name</td>
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<tr>
<td>Patient Address</td>
<td>1900 Overbrooke Drive, Allentown, PA 19107</td>
</tr>
<tr>
<td>Pt’s Relationship to insured</td>
<td>self</td>
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<td>F</td>
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<td>Patient’s DOB</td>
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<tr>
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<td>Gina Mateja</td>
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### Clinical Trial Case Details in IDX

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<td>01/01/16</td>
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<td>REACH</td>
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**Patient:** STRALOTEST DDS, SUSAN  
1900 OVERBROOKE DRIVE  
ALLENTOWN, PA  
MRN: 16003204  
SSN: XXX-XX-7123  
DOB: 02/27/2005  
FSC: ARC9.A
**Clinical Trail Case Details in IDX**

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<tr>
<td>Acct No</td>
<td>16003204</td>
</tr>
<tr>
<td>Pat Emp</td>
<td>METHODIST HOSPI</td>
</tr>
<tr>
<td>Pat FSCs</td>
<td>PT ENR</td>
</tr>
<tr>
<td>Open Cases</td>
<td>2</td>
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<tr>
<td>Closed Cases</td>
<td>0</td>
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<td>Case Status</td>
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<tr>
<td>By</td>
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<tr>
<td>Description</td>
<td>ECOG</td>
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<tr>
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<tr>
<td>Billing Insurer</td>
<td>CASE-CLINICAL TRIALS</td>
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<tr>
<td>Case Guarantor</td>
<td>16003204</td>
</tr>
</tbody>
</table>

Jump to page:
Clinical Trail Case Details in IDX

Case: 448184
Name: STRALOTEST DDS,SUSAN
Employer: METHODOIST HOSPITAL
Ins Co Name: KIMMEL CANCER CENTER
Ins Nm Over: KIMMEL CANCER CENTER
Addr 1: 490 JEFF HALL
Addr 2: 
City,State: PHILADELPHIA, PA Zip: 19107
Auth/Ref #: 
Author Date: 
Adjustor: KAREN GOSIK Phone: 215-955-2579
Donor's 2ndary Ins (y/n): 
Medicare is 2ndary because: 
Disability From: 
To: 
Acct No: 16003204
PT ENR: 
State of Accident: 
Injury Type: 
Injury Date: 
Carrier Claim: 080-30000-K78665 
Policy No: IRB#124K.345
Eff Date: 
Insured's Name: STRALOTEST DDS,SUSAN
Insured's Addr 1: 1900 OVERBROOKE DRIVE
Insured's City,State: ALLENTOWN,PA Zip: 19107
Insured's Phone: 215-434-5654
Pt Rel to Insured: SELF
Insured's Sex: F
Insured's DOB: 02/27/2005
Insured's Employer: METHODOIST HOSPITAL
Schedule Clinical Trial Service

- **Communication** between all servicing areas is an integral component to correct and compliant Clinical Trial billing.

- When requesting services covered under a clinical trial from another department, clearly communicate that the services are covered under a clinical trial and supply the **IDX Case#** and **Study#** (e.g., 080-XXXXX-JXXXXX).

- Utilize “**Clinical Trial**” stamp on ordering paperwork.
E-mail to:
Roseann.ponzio@jefferson.edu
Christina.vettese@jefferson.edu
Linda.Dobrzanska@jefferson.edu
Ed.Dungan@jefferson.edu

JEFFERSON UNIVERSITY PHYSICIANS
CASE INFORMATION

IDX MRN/Account #  16003204
Patients Name  Susan Stralatest, DDS
Type of Case  ☒ Clinical Trial

Description of Clinical Trial  ECOG

Department Name  Kimmel Cancer Center – CRMO/BMT
                  Kimmel Cancer Center – CRMO - 490 Jeff Hall
                  Philadelphia, Pa 19107
Billing Address

Study Coordinator Name  LouEllen Daniel
Study Coordinator Number  215-503-5390
Patient Enrollee  003
IRB #  13D.352
Medicare Patients Only)  http://clinicaltrials.gov/ #  NCT01982682
Grant ID  080-30000-K78665
Date of First Service to Study  6-13-16
End Date
Patient Name  Susan Stralo, DDS
Patient Address  1900 Overbrooke Drive, Allentown, PA 19107
Pt’s Relationship to insured  self
Patient’s Sex  F  Patient’s DOB  2-27-2005
Contact Name  Gina Mateja
Contact #:  215-503-0448
“Link” Clinical Services to Case

• Services can be linked in 2 ways:
  • At time of scheduling
  • At charge entry

• It is important to understand if services being rendered are part of a clinical trial
<table>
<thead>
<tr>
<th></th>
<th>Hospital JeffChart Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Assign “P99” insurance plan code in <strong>Primary Insurance Plan Code</strong> field</td>
</tr>
<tr>
<td>2</td>
<td><strong>Grant#</strong> (e.g., 080-XXXXX-JXXXX) entered as the <strong>Policy Number</strong></td>
</tr>
<tr>
<td>3</td>
<td><strong>IRB#</strong> entered in the <strong>Group Field</strong> (found on the case form)</td>
</tr>
<tr>
<td>4</td>
<td><strong>National Clinical Trial</strong> (NCT) entered in the <strong>Group Name</strong> field</td>
</tr>
<tr>
<td>5</td>
<td><strong>Grant/Clinical trial department</strong> entered as the <strong>Billing address</strong></td>
</tr>
</tbody>
</table>
| 6 | **Health insurance** (unless it is a Medicare Managed Care) entered as a secondary or tertiary, when applicable  
   Medicare Managed Care plan, register as traditional Medicare secondary and the Medicare Managed Care plan as tertiary  
P99 must ALWAYS be listed as the Primary |
Billing Office Reconciliation

- **JUP**
  - Monthly files are run for all services related to clinical trial
  - Entered into an excel file
  - Sent to JCRI for distribution and reviewed by Clinical Trial Coordinators
  - Once returned, any services identified as standard of care appropriate services are then compiled by trial number and charged to the clinical trial via IDT
Billing Office Reconciliation

- TJUH
  - Bills are generated and reviewed to determine if services qualify as Standard of Care or Study specific
  - Bills forwarded to JCRI for payment
  - Standard of Care charges are billed to insurance
Clinical Trial Charges

• **JUP**
  - 128% of 2009 Medicare, adjusted for new services 128% of the current years Medicare rate

• **TJUH**
  - Standard rate for hospital services (excluding Laboratory and Radiology) is 27.00%
  - Based on published Cost to Charge Ratio calculated by PHC4 for fiscal year 2015

  • Medicare Laboratory Fee Schedule and Radiology APC rates are effective January 1, 2016
Coding and Billing for Routine Costs of Clinical Trial
Diagnosis and Modifier Usage

- Medicare’s Clinical Trial Policy and Investigational Medical Device Regulations require specific codes and modifiers be added to claims for processing and segregation of research charges. The following is a glossary of the current Medicare requirements:

  - **Diagnosis code Z00.6** – Examination of participant in clinical trial
  - **Procedure Code Modifier Q0** – Investigational clinical service are items as those being investigated as an objective within the study
  - **Procedure Code Modifier Q1** – “Routine costs” as defined by the Clinical Trial Policy
<table>
<thead>
<tr>
<th>Item or Service</th>
<th>Q0 Modifier</th>
<th>Q1 Modifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigational drug or device provided in a qualifying clinical trial</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Protocol directed “routine cost” item or service provided in a qualifying clinical trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Typically provided absent a clinical trial</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>- Provision of the investigational item/service</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Clinically appropriate monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Required for the prevention, diagnosis or treatment of a research related adverse event</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Protocol Related Item or service</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Items Provided Free of Charge

- Claims for Investigational Devices provided free of charge must include:
  - Revenue Code 0624 (FDA Investigational Devices) with the Q0 modifier (Investigational Clinical Service) and a token charge

- Claims for Investigational Drugs provided free of charge when drug administration charges are included on the claim should include:
  - Q0 modifier (Investigational clinical service) and a token charge
Important Numbers

- **JUP Central Registration**
  - Roseann Ponzio  3-3477

- **Patient Access**
  - Outpatient Access - Michele Innaurato - 5-6016
  - Admissions - Mary DeSantis - 5-0588
  - Insurance Verification - Naim Robinson - 5-6689

- **Clinical Trial Billing & A/R Management**
  - JUP:  Merle Charlton, III - 3-3311
  - TJUH:  Ed Dunigan - 5-2521

- **Self Pay/Financial Counseling**
  - Joelle Morales  5-7889

- **Revenue Integrity and Billing Compliance**
  - Robin Brown-Stovall  3-2684