Centralized Coverage Analysis
Agenda

• Welcome
• Delivering on Our Commitment
• Importance of the Research Billing Compliance Program
• Overview of Regulations and Guidelines
• Overview of Current and Future State
• Transition Plan and Process Changes
• Questions
Delivering on Our Commitment

Guiding principles:

- Benefit all investigators
- Balance compliance with customer service
- Support implementation and operations
- CTMS; single system of record to enable enterprise and regulatory reporting
- Reduce administrative burdens
- Minimum footprint
- Reinforce CTMS use
- Leverage integration to reduce data entry and promote data integrity
- Provide free services to reduce institutional risk
- Standardize processes where possible
- Preserve operations of existing CTMS users

TRACTS: Transforming clinical Research Administration, Culture, Technology & Service
Delivering on Our Commitment

UK TRACTS Project promised:

• **Collaboration** among UK Healthcare, VPR, College of Medicine, and CCTS
• **Transformation** of administrative practices to be more efficient
• Active **engagement** of study teams in the design and delivery of services to support them
Delivering on Our Commitment

Our patients deserve:

• Access to innovated treatments and cutting-edge research
• Information about trial participation costs
• Accurate bills
• Timely issue resolution

Dr. Andrew Leventhal with Ms. Priscilla Riley, patient enrolled on the COMPASSION 3 clinical trial
Delivering on Our Commitment

• A strong research billing compliance program
  • Protects the reputation of our organization and investigators
  • Ensures UK is following regulations and federal guidance
  • Supports compliant and well-documented processes and decisions

• Centralized Coverage Analysis meets these objectives
  • Use Medicare as the "Gold Standard"
  • Leverages expertise of staff
Importance of a Research Billing Compliance Program

Historical context of Medicare & clinical trials

1995: Medicare coverage of investigational devices

2000: CMS developed the Clinical Trial Policy (CTP)

2005: Rush University settlement drew attention to the CTP

2007: CMS made slight changes to the Clinical Trial Policy (CTP)

2010:

2011: HHS Secretary Kathleen Sebelius announced that HHS has “begun several initiatives” to address inconsistencies in clinical research billing compliance

2017: Department of Justice False Claims Act - Civil Penalties - mandates minimum $10,897 per claim
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

Patient Impacts
- Patient billed incorrectly
- Copayment / coinsurance errors
- Patient frustration

Institutional Impacts
- Costs associated with investigation
- Civil fines and criminal penalties
- Under billing
- Increased governmental scrutiny
- Costs to implement corrective action plan

Investigator Impacts
- Loss of governmental funding
- Loss of trust by sponsor
- Loss of trust by patients
The research billing process is complex and requires coordination and harmonization among partnering entities.
Overview of the Regulations and Guidelines

Medicare Clinical Trial Policy (2007)

Medicare’s current Clinical Trial Policy (CTP) as of July 9, 2007

• “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.”

www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html
Overview of the Regulations and Guidelines

Medicare Clinical Trial Policy (2007)*

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; and
• 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.

*Full text can be found at:
Purpose and Benefits of a Coverage Analysis

- Early Detection of Items and Services as Non-Covered
- Tool to Ensure Compliant Claims Processing
- Increased Revenue Opportunities
- Trust of Sponsors and CROs

Coverage Analysis = Tool

COMPONENTS:
- Compliance
- Budgeting
- Claims Review
Research Billing Compliance Program

Coverage Analysis: Current state

PI/Study Team determines “standard of care” and “above standard of care”

Compliance office confirms work is complete

Budget development loosely tied to coverage analysis
Research Billing Compliance Program

Coverage Analysis: Future state

1. CRSO Coverage Analyst documents qualifying trial status
2. CRSO Coverage Analyst determines services using routine cost standard, and document in OnCore
3. Study Team review period
4. CRSO Research Billing Integrity Manager sign-off
5. Budget development cannot occur until Coverage analysis final

Compliance Monitors Process
Clinical Research & Revenue Cycle Process

**Future, future state**

- **Clinical Research Process**
  - Sign CDA
  - Protocol Review/Decision to Proceed
  - Initiate Regulatory, Financial, and Legal Review
  - CA and Budget Development
  - Study Initiation
  - Consent and Enroll Patients
  - Visit and Milestone Tracking
  - Sponsor Invoicing
  - Study Close-Out

- **Revenue Cycle Process**
  - Scientific, COI, Feasibility, and IRB Review
  - Patient Identification
  - Registration
  - Charge Segregation
  - Coding
  - Claim Processing & Invoicing

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.

This process will be streamlined as technology limitations allow. Additional future statute changes to coincide with new EHR.
Research Billing Compliance Program
Coverage Analysis: Transition plan

Happening Now

• Introduction and education for new CA process
• Align appropriate order of events: coverage analysis prior to budget
• CA completed
• CRSO provides CA in Excel to Study teams for budget development

April 2019 and Beyond

• Retraining to coincide with OnCore training based on sprint
• Formal Intake Meeting with CRSO
• Excel grids converted to OnCore as part of legacy build
• CA completed and routed via future state work flows in OnCore
Research Billing Compliance Program
Immediate changes

- **Study Team**: Complete submission form, provide protocol and supporting documents to CRSO.
- **CRSO or Huron Research Office**: Complete coverage analysis and qualifying trial criteria.
- **CRSO**: CA provided in Excel format to Study Teams.
- **Study Team and CRSO**: Review CA, request changes via review meeting.
- **Study Team or CRSO**: Final document compared to study budget; items designated ‘Research’ must be supported by study funds.

TRACTS: Transforming clinical Research Administration, Culture, Technology & Service
Research Billing Compliance Program

Submission form

- Form Location:
  - eForms

- Single Page:
  - Protocol and Contact Info
  - IRB Submission Status
  - Billable Services Information
  - Optional Comments
Research Billing Compliance Program

Supporting Documents

Required Supporting Documents:

- Final Protocol
- Draft Consent(s)
- Draft Sponsor Budget (if applicable)
- Draft Clinical Trial Agreement (if applicable)
- IND or IDE documentation (if applicable)

What will be reviewed:

- All required items specified in the Protocol and ICF and the time points
- Review of Treatment Guidelines to determine which items are conventional care
- Review of National and Local Coverage Determinations, as well as other Medicare rules and regulations
Does this apply to my study?

Submission scope

SUBMIT TO: CRSO@l.uky.edu

• This process is applicable to any human subject clinical trial that might generate a charge that could be billed without regard to:
  • Payment Source: items of service that are directed to patient/insurance for payment and those directed to research/the study account
  • Funding Source: industry, foundation, federal, cooperative group or internally funded trials

• When in doubt, submit it to avoid delays
• If you’re still not sure, contact the CRSO for help
How will this impact study activation times?

Coverage Analysis Turnaround

CURRENT PATHWAY
- Budget Development
- IRB Submission and Review
- ICA Process
- 4-6 weeks

FUTURE PATHWAY
- Coverage Analysis
- Budget Development
- 3-4 weeks
- IRB Submission and Review
When does this new process begin?

March 1, 2019

Any trial that was not submitted to UKHC Compliance (Rebecca Scott) by March 1, 2019 must follow this process.

SUBMIT TO: CRSO@l.uky.edu
What about amendments?

Submission of amendments

• All clinical trial amendments submitted to IRB after March 1, 2019 should be submitted for coverage analysis using the intake form
• CRSO will review amendments to determine impact to billing grid
• Purely administrative changes need not be submitted
How do I get a plan code?

Plan code process is not changing:

• Plan codes are what hold charges for appropriate routing in the billing system

• Following receipt of the account number from OSPA, Study Team will continue to request the plan code as they currently do
Coverage Analysis (CA)

What to expect from the CA

• Excel based document with two tabs
  • Tab 1 contains
    • Protocol Demographic Information
    • Qualifying trial status
  • Tab 2 contains
    • Billing grid and designations
    • Coding
    • Billing Justifications
Tab 1: Study information

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please list the protocol name:</td>
<td>A Randomized Multicenter Pivotal Study of HCG-0123 in Patients with Metastic, Triple-Negative Breast Cancer</td>
</tr>
<tr>
<td>Please list the Sponsor’s protocol version and/or date:</td>
<td>Version 1 / January 1, 2015</td>
</tr>
<tr>
<td>Please list the Principal Investigator’s (PI) Name:</td>
<td>Jane Doe, MD</td>
</tr>
<tr>
<td>Please list the names of the Financial Sponsor(s):</td>
<td>National Institutes of Health (NIH)</td>
</tr>
<tr>
<td>Please list the National Clinical Trial (NCT) #:</td>
<td>NCT12345678</td>
</tr>
<tr>
<td>Please list the Institutional Review Board (IRB) ID #:</td>
<td>IRB12-123</td>
</tr>
<tr>
<td>What is the version and/or date of the IRB approved Informed Consent Form (ICF)?</td>
<td>The IRB Approved Informed Consent Form (ICF) was approved on: December 15, 2014</td>
</tr>
<tr>
<td>What is the version and/or date of the executed Clinical Trial Agreement or Grant?</td>
<td>The executed Clinical Trial Agreement is dated: November 1, 2014</td>
</tr>
<tr>
<td>What is the name of the investigational item, procedure or service:</td>
<td>HCG-023</td>
</tr>
<tr>
<td>Is this a drug, device, or procedure study?</td>
<td>Drug or Biologic Study, please go to question number 11.</td>
</tr>
<tr>
<td>Qualifying Clinical Trial Analysis</td>
<td>Response</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Is this study required by Medicare as a part of the &quot;Coverage with Evidence Development&quot; process?</td>
<td>NO, this is not applicable to my trial. Please go to the next question.</td>
</tr>
<tr>
<td>Is this drug or procedure typically covered by Medicare / Medicaid (it is in a benefit category)?</td>
<td>Yes, Drugs and Biologics</td>
</tr>
<tr>
<td>Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).</td>
<td></td>
</tr>
<tr>
<td>Does the study have therapeutic intent stated in the study objective(s) or aim(s)?</td>
<td>YES, it is stated this way: “To evaluate the anti-cancer activity of HCG-0123 in metastatic, triple-negative breast cancer as measured by the duration of progression-free survival (PFS)”</td>
</tr>
<tr>
<td>Does the study enroll subjects with a diagnosed disease, (not healthy volunteers only)?</td>
<td>YES, the disease under study is: Triple-negative breast cancer</td>
</tr>
<tr>
<td>What is the FDA Status of the Drug?</td>
<td>It is provided under IND # 012,345. This is a Qualifying Clinical Trial and reimbursement for routine costs may be sought from Medicare. The remaining questions on this tab may be skipped.</td>
</tr>
<tr>
<td>Is the study funded by NIH, CDC, AHRQ, CMS, DOD, or the VA?</td>
<td>N/A</td>
</tr>
<tr>
<td>Is the study supported by cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or the VA?</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Tab 2: Billing Grid

<table>
<thead>
<tr>
<th>Designations</th>
<th>Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Routine Cost</td>
</tr>
<tr>
<td>R</td>
<td>Non-Routine Cost (Research)</td>
</tr>
<tr>
<td>X</td>
<td>Cannot determine</td>
</tr>
</tbody>
</table>

### Protocol Related Items and Services

<table>
<thead>
<tr>
<th>Protocol Related Items and Services</th>
<th>Location in Protocol or ICF</th>
<th>CPT / HCPCS Codes</th>
<th>Q0 or Q1 Modifier</th>
<th>Visit Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Treatment Visits</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cycle 1 Day 1</td>
</tr>
<tr>
<td>Investigational Drug: HCG-0123 (IV)</td>
<td>p. 15</td>
<td>J9999</td>
<td>Q0</td>
<td>R</td>
</tr>
<tr>
<td>Premedication: Aloxi (IV)</td>
<td>p. 15</td>
<td>J2469</td>
<td>No</td>
<td>R</td>
</tr>
<tr>
<td>Premedication: Dexamethasone (IV)</td>
<td>p. 15</td>
<td>J1100</td>
<td>No</td>
<td>R</td>
</tr>
<tr>
<td>IV administration</td>
<td>p. 15</td>
<td>96413, 96415, 96417, 96365, 96366, 96367</td>
<td>Q1</td>
<td>S</td>
</tr>
<tr>
<td>Capecitabine (PO)</td>
<td>p. 38</td>
<td>J8520, J8521</td>
<td>Q1</td>
<td>S</td>
</tr>
</tbody>
</table>

Per the draft study budget, this item is paid for by the sponsor.

This item is required for the provision of IV medications used in the study. Coverage supported by NCD 310.10.

According to NCCN guidelines for Breast Cancer (v3.2015), this treatment regimen is considered conventional care.
What if I disagree?

Review and decision adjudication

• PIs and Study Teams will be given the information and the CRSO will assist in education the teams on how to use the grid
• The study teams and PI will be given a chance to provide feedback, and ask questions
• The Coverage Analysis will provide justification for decisions and will discuss these directly with the PI and the study team
• Issues may be escalated to department chair, unit director, review committee
What about revenue cycle?

How does this change charge segregation?

- Study teams should use the CA for their budgeting process
  - Items eligible for Medicare billing may still be paid by the sponsor
  - Items **ineligible** for Medicare billing **cannot** be billed to Medicare
  - If the sponsor pays for an item of service, it is not to be billed to Medicare or third-party payors
- Charge segregation point of contact will shift to CRSO post OnCore implementation
- Revenue Cycle team will use CA to define claim processing decisions
Wrap Up

• CA is a collaborative process
• Study teams should utilize CRSO staff to assist in tracking and resolving research participant billing complaints
• We welcome your ongoing feedback

Questions?
Contact: Anne Wray, CRSO Operations Program Director, Interim 
Jessica Heskel, CRSO Clinical Trials Financial Manager
Human Subject Research in the College of Engineering: Participant Recruitment Experience in the Human Musculoskeletal Biomechanics Lab

This presentation will provide an overview of research conducted in the human musculoskeletal biomechanics lab in the college of engineering. This will include the studies on age and work-related changes in biomechanics of the human lower back. Methods used and challenges faced in the lab for participant recruitment will also be discussed.

DATE
Thursday, February 21, 2019

TIME
12:00 – 1:00 pm
(Pizza served at 11:50 am)

LOCATION
MN 463

Presented by:
Babak Bazrgari, PhD
Associate Professor, F. Joseph Halcomb III, MD
Department of Biomedical Engineering
College of Engineering
University of Kentucky