Research Billing Compliance
Building Blocks to Success
Beth Kubista
Sanford Health

Objectives
- Clinical Research Billing (CRB) Risks
- Auditing and Monitoring
- Lessons Learned

Where is the CRB Risk?
- Billing
- Coverage Analysis
- Service, Provider and Patient Identification
- Documentation
CRB Risks

- Billing for services the sponsor is already paying for
- Billing for service promised free to the participant
- Billing for services that are for research purposes only
- Billing for services that do not qualify for coverage:
  - Non-qualifying trial
  - Statutorily excluded
  - LCD/NCD restrictions
- Billing Medicare Advantage when traditional Medicare should be billed

CRB Risks Continued...

- Having no or an incomplete coverage analysis
- Determining a qualifying trial
- Lack of consistency
- Lack of internal processes for:
  - Identifying research patients correctly
  - Identifying research services
  - No or insufficient documentation to support medical necessity or trial participation

Reducing the Risk - Billing

You must not bill for services:
- The sponsor is already paying for
- Promised free to the participant
- That are for research only
- That do not qualify for coverage:
  - Non-qualifying trial
  - Statutorily non-covered
  - LCD/NCD
- To Medicare Advantage when they should go to Medicare
Reducing the Risk – Billing Medicare

- NCD 310.1 Clinical Trial Policy
  - Covers routine costs of qualifying clinical trial as well as necessary items and services used to diagnose and treat complications arising from participation.
  - All other Medicare rules apply
- Medicare Benefit Policy Manual
  - Chapter 14 (Medical devices) and 15 (other services)
- Medicare Claims Processing Manual
  - Chapter 32 (Billing Special Services)

Routine Costs

- Typically provided absent a clinical trial (conventional care)
- Services required for the provision of the investigational item or service (administration of drug)
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service (complications)
- Does not include:
  - Investigational item or service unless it would be covered outside a trial
  - Items and services solely for research purposes (frequent lab work, imaging)
  - Items and services provided free of charge
Reducing the Risk – Coverage Analysis

A coverage analysis is a tool that helps:
- Determine if a qualifying trial
- Determine billable services -
- Determine correct claim information
- Document reasoning

Benefits:
- Assist with budgeting
- Assist IT with EMR edits and builds
- Tool for billing office to follow
- Monitoring and auditing

Sample Coverage Analysis

<table>
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<tr>
<th>Protocol</th>
<th>MODS</th>
<th>V1</th>
<th>C2D1</th>
<th>C2D8</th>
<th>C2D15</th>
<th>C3D1</th>
<th>C4D1</th>
<th>MCA Source</th>
<th>Drug ABC Q0</th>
<th>NB</th>
<th>NB</th>
<th>NB</th>
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</thead>
</table>

Drug ABC will be “provided centrally by the Sponsor” (Protocol, p. 53).

IV CHEMOTHERAPY ADMIN Q1

Coverage for the administration of the investigational agent “Drug ABC,” is supported by NCD 310.1.

OFFICE VISIT ALL Q1

A physical exam is considered conventional care at clinical presentation and workup (NCCN Guidelines, p. 23). A physical ... to detect, monitor and treat potential side effects of the study drug. Coverage supported by NCD 310.1

HCG SCREEN N/A

Fetal side effects of Drug ABC have not been proven with human data. This item will be done for research purposes when performed at screening and 2nd course C1D1.

PROTHROMBIN TIME (PT/INR) N/A

NCD 190.17 limits coverage for PT/INR testing to patients within certain disease classes that are not recognized in this study (NCD 190.17). Coverage limited by NCD 190.17.

Reducing the Risk – Patients and Staff

Who is involved in research?
- Principal Investigator
- Clinical Research Coordinator
- Budget team
- IRB team
- Grants
- HIM

But did you think about…
- HIM
- Registration/scheduling
- Billing and Coding teams
Reducing the Risk – Patients and Staff

Think about:
- Who your patient population is and how you identify them
- Billing and coding need to identify research patients to code correctly
- Rural area patients
- Location of services
  - Communication of clinical research billing to all locations
  - Imaging
  - Lab
- Who is providing the service?
  - Obligation to outside entities that see your research patients?

Reducing Risk - Documentation

- There must be supporting documentation and medical necessity for all services related to the research study that you are billing for.

Consider:
- Documentation of reasoning for study participation
- Pre-authorization

Auditing and Monitoring

Auditing
- Risk analysis
- Gaps
- Determine frequency
- Audit plan
- Define scope... and stick to it!
- Type of audit
- Universe
- Most helpful:
  - Study Protocol
  - Informed Consent Form (IRB Approved)
  - Final contract and Budget
  - FDA Status Letters (IDE/IND)
  - Coverage Analysis
Audit Process Planning Tool

Audit Process Planning Tool

Auditing and Monitoring

Monitoring
- Newly approved studies
- Check billing immediately
- Are edits working?
- Studies that have been amended that require a billing change

Lessons Learned

- "Understand" the Medicare rules for clinical trials
- Be consistent in your practices
- Increase focus on training and education
- Be patient