Research Billing Compliance

Building Blocks to Success

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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 no qualify for coverage:
  - Non-qualifying trial
  - Statutorily excluded
  - LCD/NCD restrictions
- Billing Medicare Advantage when traditional Medicare should be billed

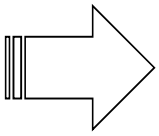
CRB Risks Continued…

- 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



COVERAGE ANALYSIS

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)

Reducing the Risk – Billing Medicare

- 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 service 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

Type of Study	Hospital Inpatient	Hospital Outpatient	Professional	Reference
Clinical Trials Involving a Category A IDE	• Approval of Medicare contractor required prior to billing – • Device is not eligible for payment –put in non covered on claim with FB modifier if provided at no cost • Routine care to provide the device may be covered • Follow CT billing instructions below for coding	• Approval of Medicare contractor required prior to billing • Device is not eligible for payment • Routine care to provide the device may be covered • Follow CT billing instructions below for coding	• Approval of Medicare contractor required prior to billing • Report IDE # on Item 23 • Follow CT billing instructions below for coding	Medicare Claims Processing Manual Chapter 32 §68.3 & §69.6 **Medicare Benefit Policy Manual Chapter 14**
Clinical Trials Involving a Category B IDE	• Approval of Medicare contractor required prior to billing • Report IDE # (if device has a G code) in FL 43 description with 0624 revenue code as covered charges in FL42* • Do not bill for device if provided free of charge from sponsor • Follow CT billing instructions below for coding	• Approval of Medicare contractor required prior to billing • Report IDE HCPCs code (if applicable) with 0624 revenue code • Include the IDE G# in FL 43 description • Bill as covered charges. If device is provided at no cost add condition code 53 and Value Code FD. • Follow CT billing instructions below for coding	• Approval of Medicare contractor required prior to billing • Report IDE G in Item 23 • Follow CT billing instructions below for coding	Medicare Claims Processing Manual Chapter 32 §68.4 & §69.6 **Medicare Benefit Policy Manual Chapter 14** Chapter 4 §20.6.9 (FB modifier)
Clinical Trials (CT)	• Clinical trial and non-clinical trial services must be reported as separate line items • Services or items provided or paid for by research sponsors may not be billed. If necessary to report the device, it must be as a non-covered charge • Report Condition Code 30 • Report Z00.6 as secondary diagnosis code	• Clinical trial and non-clinical trial services must be reported as separate line items • Services or items provided or paid for by research sponsors may not be billed. • Report Condition Code 30 • Report Z00.6 as secondary diagnosis code • Attach Q1 modifier to all lines that contain a *routine service* • Attach Q0 to all lines that contain *investigational items (item may be routine care)*	• Clinical trial and non-clinical trial services must be reported as separate line items • Attach Q1 modifier to all lines that contain a *routine service* • Attach Q0 to all lines that contain *investigational items(may be routine care)* • Assign Z00.6 as secondary	Medicare Claims Processing Manual Chapter 32 §69.5 & §69.6

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:

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

Sample Coverage Analysis

Protocol Related Items and Services	MODS	Screening V1	C2D1	C2D8	C2D15	C3D1	C4D1	MCA Source
Drug ABC	Q0		NB			NB	NB	Drug ABC will be "provided centrally by the Sponsor" (Protocol, p. 53).
IV CHEMOTHERAPY ADMIN	Q1		INS			INS	INS	Coverage for the administration of the investigational agent "DrugABC," is supported by NCD 310.1.
OFFICE VISIT ALL	Q1	INS	INS	INS	INS	INS	INS	A physical exam is considered conventional care at clinical presentation and workup (NCCN Guidelines, p. 23). A physical exam performed at screening is billable. DrugABC is known to cause numerous severe side effects. A physical exam, performed at the frequency required during treatment and follow-up will be done to detect, monitor and treat potential side effects of the study drug. Coverage supported by NCD 310.1
HCG SCREEN	N/A	RP						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	RP						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
- IT

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
- Must haves:
  - Study Protocol
  - Informed Consent Form (IRB Approved)
  - Final contract and Budget
  - FDA Status Letters (IDE/IND)
  - Coverage Analysis

Audit Process Planning Tool

P	AUDIT PLANNING	NOTES (briefly describe steps, refer to documents, or date completed)
	1) Agree on deadline for audit research to be complete with assigned Director (Background)	
	Description of Risk or Issue to be Audited	
	*Describe the subject matter under review and if not a planned audit, reason it is being performed.	
	2) Identify any related, prior audits or consultant report (internal or external) (Background)	
	*Note any identified issues, recommendations, unresolved concerns, etc. that may be relevant to this audit.	
	3) Identify any related internal policies or procedures (Background)	
	4) Review available reference materials and industry information. (Background)	
	*Be able to describe any compliance requirements related to this topic.	
	*Research following sources: CMS, MAC, OIG, RAC as well any state law and other requirements.	
	*Review publications, list serves, and other available resources for information.	
	5) Obtain input from operations (Background)	
	*Ascertain level of awareness of regulatory requirements and resulting compliance risks	
	*Understand current processes related to compliance	
	*Identify controls, if any, to reduce risk of error	
	6) Define audit scope & methodology	
	*Determine specifically what will be audited and the reference for the audit criteria	
	*Prepare the audit tool describing specific audit criteria	
	*Specify source of audited information (progress notes, claim forms, detailed bills, therapy logs, etc.)	
	*Determine number of samples to be audited	
	*Specify a date range to select sample	
	For billing related audits:	
	*Decide if pre-payment or post-payment data will be reviewed	
	*Define the payer mix of claims to be audited	
	*Set threshold for re-audit or if N/A	
	*Determine what errors will require correction to claims	
	7) Review with assigned Director	
	*Review all audit planning activity described above	
	*Pay special attention to clarity of the audit scope	
	*Define timeline for audit completion by location, region, etc.	
	*Share plan with directors and others as necessary for group input and agreement to all aspects of audit	

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


Questions?