PREP Course #10: Coverage Analysis

Presented by:

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The Feinstein Institute for Medical Research
North Shore LIJ
NQF National Quality Forum
National Quality Healthcare Award Winner 2010

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- Course Director, Kevin Tracey , has disclosed a commercial interest in Setpoint, Inc. as the cofounder, for stock and consulting support. He has resolved his conflicts by identifying a faculty member to conduct content review of this program who has no conflicts.
- Emmelyn and Danny have nothing to disclose.

Today's Objective

- Describe the process for performing a Medicare Coverage Analysis (MCA)

We Will Discuss the Following

- Federal and local requirements related to coverage analysis as it relates to research billing
- Benefits of performing a coverage analysis and how it can be used during sponsor negotiations
- Coverage analysis process

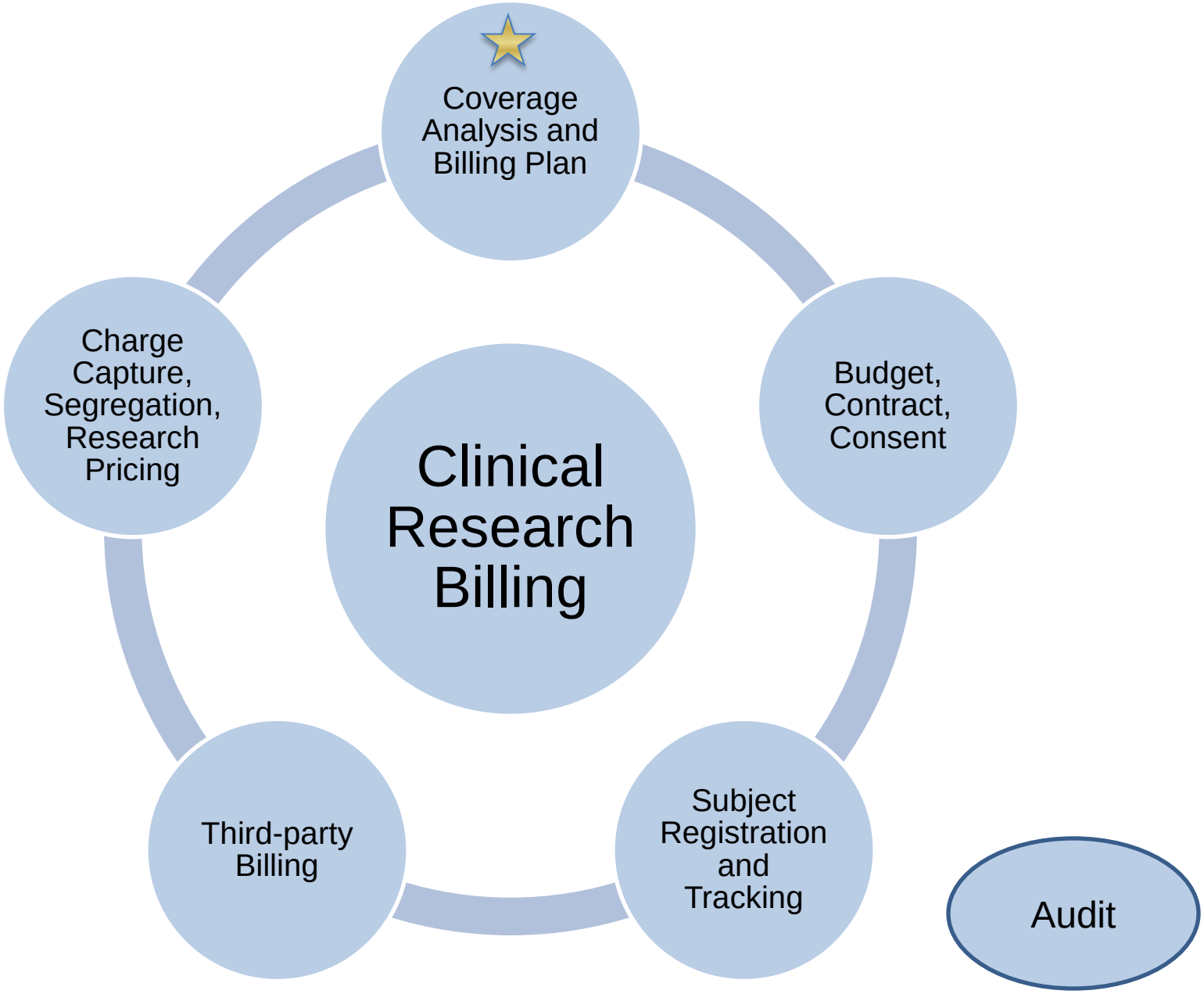

Diagram from Meade & Roach, LLP

What Steps are Involved in a Coverage Analysis?

1) Determining if the trial is qualifying
2) Analyzing cost uniformity among study documents
3) Developing a billing grid
4) Determining whether Medicare can be billed for the items and services provided to research subjects

What are Benefits of Performing a Coverage Analysis?

- Provides research subjects with accurate information related to costs of the CT
- Determine true costs of the the CT, which you can use to negotiate with sponsors
- Provides protection from violation of false claims act and other regulations
- Allows for appropriate billing
- Provides documentation of determinations

What Does It Mean to be a Qualifying Trial?

- It means items and services may potentially be billable to Medicare

→ Remember that Medicare will pay for certain routine costs

Clinical Trials Coverage

Medicare National Coverage Decision (NCD) for Clinical Trials (CTs) covers:

- Routine costs of qualifying clinical trials
- Reasonable & necessary items and services used to diagnose and treat complications from participating in CTs

CMS=Center for Medicare & Medicaid Services

Federal Requirements

CMS Documents:

- National Coverage Determinations (NCDs)
  - Clinical Trials Policy
- Devices: Medicare Benefit Policy
- Manuals
- Transmittals – use of billing modifiers (Q1, Q0 for clinical research)

Step 1a: Determining Whether Your Trial is Qualifying

As outlined by the Clinical Trials Policy, the trial must meet the following:

1. Evaluates an item or service that falls within the Medicare benefit category
2. Have therapeutic intent
3. Enroll patients with diagnosed disease

AND

Step 1b: Qualifying Trial (Cont'd)

Be one of following types of trials deemed to meet the 7 desirable characteristics:

1. Funded by NIH, CMS, AHRQ, DOD, VA or CDC
2. Supported by centers or cooperative groups funded by NIH (e.g. GOG, CALGB, COG, SWOG, etc.)
3. Conducted under an investigational new drug application (IND) reviewed by the FDA
4. IND exempt with exemption letter from FDA

Exercise: Use the MCA Checklist

Questions:

1. Is this a qualifying trial?

2. Provide your reasoning for your answer

Step 2: Analyzing Cost Uniformity

- Analyze cost uniformity among study documents:
  - Consent form (procedures & cost language)
  - Protocol (Schedule of Events)
  - Funding document (contract)
- Determine what's covered by the sponsor
- Clarify any discrepancies with sponsor
- Ensure final documents are updated

Exercise: Analyzing Cost Uniformity

Questions:

1. Is there harmonization among all study documents?
2. Provide your reasoning for your answer

Step 3: Developing a Billing Grid

Sponsor:	NIH	
Study Title:	TruBeta Trial	**R = Research, Sponsor Pays**
P.I.:	Jonas Jordan, MD	**S = Standard of Care / Routine Costs, Patient or Insurance Pays**
Campus:	Feinstein Institute	**N = No Funding (not covered by sponsor or insurance)**

Protocol Schedule of Events	**Visit Number**						
	1	**2**	**3**	**4**	**5**	**6**	**7**
Coverage Analysis	Baseline Screening	Final Screening	Day 0	Week 2	Month 1	Month 3	Month 6
Informed Consent							
Medical History							
Concomitant Medications							
Adverse Events							
Physical Exam							
Vital Signs, Height, Wt, BMI							
Study Drug							
Procedures:							
Vascular Ultrasound							
MRA Whole Body							
Lab Tests:							
Complete Blood Count							
Comprehensive Metabolic Panel							
HbA1c							
Pregnancy test							
Glucose Testing							

Why Develop a Billing Grid?

- Allows one to indicate clear charge direction for each procedure during each visit
  - E.g. research vs. routine
- Creates transparency
  - Use as a universal document for research billing
  - Allows for ease of third party review

Research Costs

- Are items or services covered by the research sponsor as per the contract and consent form

Note the following:

- Sponsors may even cover routine costs and may pay for costs the subject's insurance won't cover
- If the consent form the subject signs erroneously says that procedures will be covered by the research study, you will have to eat the cost!

Routine Costs

Items or services:

- Typically provided during conventional care
- Required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item/service or prevention of complications
- Needed for reasonable and necessary care arising from provision of an investigational item or service or treatment of complications

Routine Costs Are Not…

Items or services:

- That are statutorily excluded or where there is a non-coverage decision
- Which are investigational
- Provided solely for data collection & analysis
- Provided by research sponsors at no cost to the subjects

Exercise: Completing Billing Grid Charge Direction

1. Enter “R” for any item or service that is covered by research

2. Enter “S” for any item or service that not covered by research and appears to be standard of care

Step 3: Determining What is Covered by Medicare for Items Marked as "S"

→ Start with National Coverage Decisions

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Local Coverage Decisions (LCDs)

Local Medicare Contractor :

- NY - NGS National Government Services www.ngsmedicare.com
- Includes determinations by Medical Director
- Find LCDs on www.cms.gov

Finding LCDs on www.cms.gov

SUBMIT

RESET SELECTION CRITERIA

LCDs by State Index Results

[4 Contractors]

Your Selection Criteria Were: **States(s)**: New York - Entire State

Print Report

Expand All | Collapse All

New York - Entire State [4 Contractors]

MAC PART B / PART B CARRIERS	MAC PART A / PART A FISCAL INTERMEDIARIES	HOME HEALTH AND HOSPICE MAC / REGIONAL HOME HEALTH INTERMEDIARIES	DURABLE MEDICAL EQUIPMENT MACs / PSCs / REGIONAL CARRIERs
National Government Services, Inc.(13202, MAC - Part B)	National Government Services, Inc.(13201, MAC - Part A)	National Government Services, Inc.(00450, RHHI)	NHIC, Corp.(16003, DME MAC)

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Related Indexes [2 Links]

Internal Links

Local Coverage Determinations (LCDs) by Contractor Index
Local Coverage Determinations (LCDs) Alphabetical Index

Get Help with File Formats and Plug-Ins | Submit Feedback

About Devices

Category A: Experimental/Investigational
Category B: Non-experimental/ Investigational

Coverage of investigational devices if:

- On master list of IDE devices
- Reasonable & necessary – Cat B
- Dates of service within dates on master list
- No other policy that prohibits coverage

Device Coverage Determinations

Devices: require pre-authorization from the local Medicare contractor

National Government Services

→IDE PMA Request Form from www.ngsmedicare.com

→Send email to:

NGS-IDE-Request@wellpoint.com

Need to renew approval periodically

More About Coverage Determinations

Private Insurance: May need to obtain pre-authorization prior to provision of services to ensure coverage

Although many generally follow Medicare coverage decisions

Exercise: Determining Medicare Coverage

→ Review billing grid answers

Where no coverage decision exists:
•Create supporting documentation of routine care determinations

If item or service is not covered by Medicare/insurance:
→ Change any “S” to “N” which stands for “no funding” because it is not billable to subject’s insurance

Completed Billing Grid

Sponsor:	NIH	
Study Title:	TruBeta Trial	**R = Research, Sponsor Pays**
P.I.:	Jonas Jordan, MD	**S = Standard of Care / Routine Costs, Patient or Insurance Pays**
Campus:	Feinstein Institute	**N = No Funding (not covered by sponsor or insurance)**

Protocol Schedule of Events				**Visit Number**			
	1	**2**	**3**	**4**	**5**	**6**	**7**
Coverage Analysis	Baseline Screening	Final Screening	Day 0	Week 2	Month 1	Month 3	Month 6
Informed Consent	R						
Medical History	S						
Concomitant Medication	S	R	R	R	R	R	R
Adverse Events				R	R	R	R
Physical Exam	S	R	R	S	R	R	R
Vital Signs, Height, Wt, B	S	R	R	S	R	R	R
Study Drug			R	R	R	R	
Procedures:							
Vascular Ultrasound			R		R	R	R
MRA Whole Body			R				R
Lab Tests:							
Complete Blood Count	S		R	S	R	R	R
Comprehensive Metabol	S		R	S	R	R	R
HbA1c	S		R			R	R
Pregnancy test	R		R	R	R	R	R
Glucose Testing		R	R	R	R	R	R

Translating the Billing Grid to an Internal Budget

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1														
2	Sponsor:	NIH							Done at regular semi-annual visits:					
3	Study Title:	TruBeta Trial							Phys Exam, Vital Signs and EKG					
4	P.I.:	Jonas Jordan, MD							SOC = Standard of Care					
5	Campus:	Feinstein Institute												
6						Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7		Totals
7	Diagnosis:	Diabetes		Unit Cost		Screening	Fnal Screening	Day 0	Week 2	Month 1	Month 3	Month 6		
8														
23	Study Events - Per Subject Costs													
24	Informed Consent			125		125								125
25	Inclusion/Exclusion Criteria			25		25								25
26	Medical History			75		SOC								-
27	Physical Exam			125		SOC	125	125	SOC	125	125	125		625
28	Adverse Events			25					25	25	25	25		100
29	Concominant Meds			10		SOC	10	10	10	10	10	10		60
30	Vitals, Height Weight, BMI			25		SOC	25	25	SOC	25	25	25		125
31	Lab Tests:													
32	CBC			26		SOC		26	SOC	26	26	26		104
33	CMP			26		SOC		26	SOC	26	26	26		104
34	Hemoglobin A1c			30		SOC		30			30	30		90
35	Urine Pregnancy			28		28		28	28	28	28	28		168
36	Glucose Testing Kit with Strips			100			100							100
37	Procedures:													
38	Vascuar Ultrasound (Technical Component)			54				54		54	54	54		216
39	MRA (Technical Component)			512				512				512		1,024
40	Total Study Events - Subject Fees					178	260	836	63	319	349	861		2,866
41														
42	Overhead at 31%													888
43														
44	Total Per Subject Cost													$ 3,754
45						Per Subject		# of						
46	SUMMARY					Cost		Patients						
47	Enrollment Goal:		10 Patients			$ 3,754		10	37,540					
48	Start-Up Fees								14,754					

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Health System Policy

GR023: Research Billing Procedure for Outpatient Services, Inpatient Services and Ancillary Testing

Forms:

•Outpatient & Inpatient Research Subject Registration Form

•Core Lab – Special Purpose Fund Account Set up Form

→ Contact Shruti Kadakia for more information (678) 682-3409

North Shore LIJ HealthPort

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Saturday November 3, 2012

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Financial and Grant Management Compliance Notice

It is the intent to have these polices followed for all Health System Research. It is recognized, however, that certain facilities do not use the Health System's Finance Department at Westbury and have different billing systems for which these policies are not suitable. In those cases, the facilities will need to develop their own processes consistent with these policies.

Research Policies

Type	Title	Policy No
Section : Financial and Grant Management Compliance - See Above Notice (21)		
	GR022 Compensation for Research Subjects	GR022
	GR022 Research Study Participant Payment Form	GR022 Attachment
	GR047 (System #100.06) Grant Applications for External Funding	GR047
	GR047 Office of Sponsored Programs Grant Application Routing Form	GR047 Attachment
	GR047 Office of Grants & Contracts Grant Application Routing Form	GR047 Attachment
	GR041 Grant Close Out	GR041
	GR023 Research Billing Procedure for Outpatient Services, Inpatient Services and Ancillary Testing	GR023
	GR023 Medicare Outpatient Payment Rates	GR023 Attachment
	GR023 Inpatient Research Subject Registration	GR023 Attachment
	GR023 Outpatient Research Subject Registration	GR023 Attachment
	GR023 Special Purpose Fund Account Set Up Form	GR023 Attachment
	GR013 Time and Effort Reporting for Grants and Contracts	GR013
	GR013 Blank Time and Effort Certification Form	GR013
	GR013 DHHS Letter	GR013 Attachment
	GR013 Time and Effort Certification Frequently Asked Questions	GR013 Attachment
	GR054 Principal Investigators for Sponsored Research	GR054

Trusted sites 100%

Online Resources

Federal: www.cms.gov
•Clinical Trial Policy (CTP)
•Medicare Benefit Policy
NY State: www.ngsmedicare.com
Coverage Decisions: www.codemap.com

Medical Information:
National Guidelines: www.guidelines.gov
Epocrates: www.epocrates.com
Medline: www.nlm.nih.gov

FDA Drugs:

Questions?

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