

# Clinical Trials: Medicare and Standard of Care

Office of Sponsored Research, January 21, 2016

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# Who we are...

- Lisa R. Pitler: Master's prepared hematology/oncology nurse and healthcare attorney. Practiced nursing (staff nurse, CNS, CRA), managed the HIV research program at Rush, research administrator, practiced law (medical and insurance defense) and worked in hospitals, pharmaceutical industry and law firms
- Kelly A Carroll, MA, PhD: Research Scientist Navigator at Lurie Children's Hospital and previously at NUCATS in regulatory and operational roles as well as Director/Instructor of MSRC program.

# Objectives

- Difference between Clinical Research and Clinical Trials
- How to determine if something is or is not standard of care
- What to do if a procedure is standard of care

# *Basics*

**Clinical Research:** use human subjects information to better understand human health at individual or group level

**Clinical Trial:** study to assess the safety and efficacy of a health intervention

# How to read a Clinical Trial:

- Draft Consent
- Study schedule or schedule of assessments as a guide

# Sample Study Schedule

Acme Pharmaceutical Co.

Evaluation	Screening	Randomization	Double-Blind Treatment Phase					Study End/ET
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8
Visit	Day -28 to 0	Day 1	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
			(± 7 days)	(± 7 days)	(± 7 days)	(± 7 days)	(± 7 days)	(± 7 days)
Informed Consent	X							
Review inclusion/exclusion	X	X						
Medical history	X							
Physical exam	X				X			X
Vital signs	X	X	X	X	X	X	X	X
AE assessment		X	X	X	X	X	X	X
Concomittant meds	X	X	X	X	X	X	X	X
Randomization (IVRS)		X						
Study drug dispensation		X	X	X	X	X	X	
Endoscopy	X				X			X
CBC	X		X	X	X	X	X	
H. Pylori - serum	X		X	X	X	X	X	X
Urinalysis	X							
Pregnancy test		X						
PK samples			X					
Chest x-ray	X							

**Start**

**Clinical  
Trial**

**Clinical  
Trail  
Policy**



**Research  
Billing**

**Coverage  
Analysis**

**Normal  
Routine  
Care**

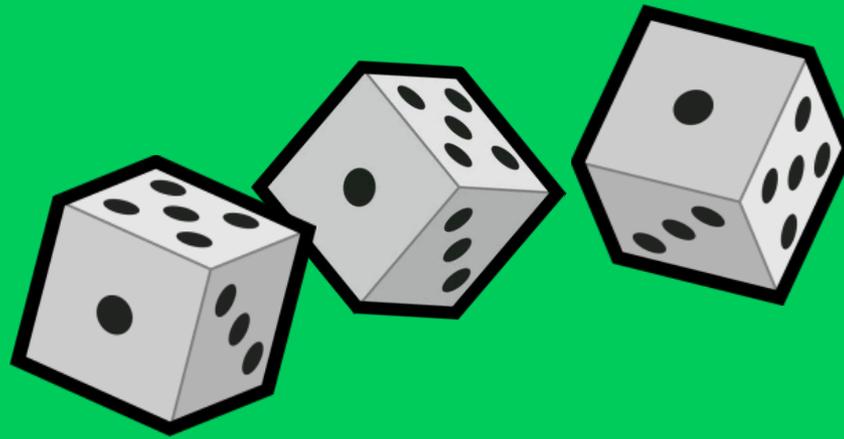
**Open  
Clinical  
Trial**

# Billing for Clinical Trials Research



?

**Device  
Clinical  
Trial**



**Qualifying  
Clinical  
Trial**

**Medicare  
Approval**



**Double  
Dipping**

**Documents  
Match**

**Subject  
Injury  
Language**

**NCD  
LCD**

?

**False  
Claim  
Act**

**Prohibited**

# *To be addressed...*

- Affordable Care Act
- Medical Necessity
- Medicare and Insurance
- NCD and LCD
- Routine Costs
- Coverage Analysis
- Subject Injury & Medicare Coverage

# *Affordable Care Act*

- Effective January 1, 2014, the ACA **requires** private insurers and health plans to cover the routine costs associated with participation in approved Phase I, II, III, IV clinical trials to prevent, detect, or treat cancer or other life threatening diseases
- Approved trials are either federally funded, under and IND or IND exempt
- ACA is not applicable to Medicare or Medicaid.

# Medicare...Then & Now

1965- Congress passed legislation establishing the Medicare program as Title XVIII and Title XIX of the Social Security Act in response to specific medical care needs of the elderly

1973- coverage expanded for certain disabled persons and certain persons with kidney disease

2000- Clinical Trial Policy, prior to this National Coverage Determination Medicare beneficiaries could not participate in clinical trials- as Medicare would not cover the costs of routine care

Then- Two parts: Hospital Insurance (HI *aka* Part A) and Supplementary Medical Insurance (SMI *aka* Part B)

Now- Four parts: Part A (Hospital coverage), Part B (Medical Insurance) Part C *aka* Medicare Advantage Plans (combines A, B and perhaps D into an HMO or PPO with a private insurer) and Part D (Prescription Drug coverage)

# *Underlying* theme...Medical Necessity

- Medicare's definition of medical necessity stems from the SSA of 1965 (1862[a][1][A]) states **no payment** under Medicare Part A or Part B for any expenses incurred for items or services which, except for certain named exceptions ...
- “are not *reasonable and necessary* for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body part”
- Not medically necessary: a particular service is not a benefit under the defined benefit, for this diagnosis, at this time (Article for Medical Necessity –A3369- WPS, 2/1/02)

# *Not medically necessary*

## **TAKE AWAY:**

In other words...when Medicare does not pay, it does not mean the service should not be ordered or performed, nor does it mean it is not “standard of care”---it simply means Medicare does not pay

# How Medicare works with other insurance

## Medicare Secondary Payer Rule/Coordination of Benefits

The primary payer pays first up to the limits of coverage

- The secondary payer pays costs the primary insurer did not cover

CMS determines the order of payment:

- Medicare tries to be the secondary payer
- Complications/Injuries arising out of clinical trials: In terms of subject injury language in a contract...if a Sponsor offers to pay, Medicare holds them out as a liability insurance plan, and the Sponsor has reporting requirements and COB (Section 111 NGHP User Guide, Chapter 6)

Key: Find out if the patient has more than one insurance

# What is the difference between Medicare & Medicaid & Private/Commercial Insurance?

- Medicare- federally funded
  - Established in response to widely perceived inadequacy of welfare medical assistance under public assistance
- Medicaid- funded federally and by the state
- Private/Commercial insurance is not funded by the government

# Medicare Coverage of Device Clinical Trials

1995 Device Regulations” Devices and Related Services 60 FR 48417

- Medicare covers the device in device clinical trials if it is a investigational device exemption (IDE) with a Category B designation
- Medicare Coverage: limited to those devices used in FDA and IRB approved studies and is case-by-case:
  - Category B IDE device clinical study
  - Category A IDE device clinical study before billing routine costs of clinical studies involving a Category A device
  - Post-market approval studies or registries of carotid stents
  - Studies for proximal embolic protection devices (EPDs) in carotid artery stenting (CAS) procedures

# National Coverage Determinations (NCD) & Local Coverage Determinations (LCD)

Underlying theme...is the item or service reasonable and necessary; provided for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body party...(and falls under a Medicare benefit category)

- National Coverage Determinations (NCDs) are statutes: they define what is covered by Medicare
- Local Coverage Determination (LCD)-aka local medical review policy (LMRP) is a decision by a fiscal intermediary (FI) or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with §1862(a)(1)(A) of the Social Security Act (e.g., determination as to whether the service or item is reasonable and necessary)
  - LCDs are developed when there is no NCD or when there is a need to further define a NCD
  - LCDs cannot conflict with NCDs

# *National Coverage Determination* (NCD) for Routine Costs in Clinical Trials (310.1) --Clinical Trials Policy (CTP)

Effective for items and services furnished on or after July 9, 2007, **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.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except...

# (NCD) for Routine Costs in Clinical Trials (310.1) --Clinical Trials Policy (CTP)

The investigational item or service, itself *unless otherwise covered outside of the clinical trial*

Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial

# What are Routine Costs?

Routine costs include items and services:

- that are typically provided absent a clinical trial
- required solely for the provision of the investigational item or service (e.g., administration of an investigational drug)
- required for the clinically appropriate monitoring of the effects of the investigational item or service
- required for the prevention of complications
- needed for reasonable and necessary care arising from the provision of the investigational item or service (e.g., diagnosis of complications)

# (NCD) for Routine Costs in Clinical Trials (310.1) --Clinical Trials Policy (CTP) (Cont)

## THREE requirements:

- The subject or purpose of trial must be an evaluation of an item or service that fall within a Medicare Benefit Category and is not statutorily prohibited
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteer. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

## Deemed to be automatically qualified are:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, DOD and VA
- Trials conducted under an investigational new drug application (“IND”) reviewed by the FDA; and
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)...until qualifying criteria are developed and certification process established

# NGS Medical Policy Article

- ...because Medicare may pay for certain costs in the study, but other payers will not ...and the study sponsor provides those items or services for free...then Medicare likewise must not be billed for those items and services. Medicare must be on a level playing field with all payer types...
- Exception: Indigent patients for whom the hospital routinely offers free care...
- Article for clinical trials- Medical policy article (A492286), NGS, [www.ngsmedicare.com](http://www.ngsmedicare.com), taken 9/27/13

# Coverage Analysis: A method to work with Medicare in the context of clinical trials

The CA provides:

- The protocol, the draft informed consent, the contract and draft budget
- Provides a template to develop and negotiate a stronger budget (who is paying for what)– *Sponsor*, *Medicare/commercial insurance*, *Subject*, or the *Department*
- Provides a template for subjects financial liability in the consent and also addresses subject injury (§46.116 and 21 CFR 50.25)
- Serves as a guide for the IRB to review the cost section of the informed consent
- NCDs and LCDs
- Tool for audits
- Consistent methodology for research billing

# *Subject Injury Language*

- Sponsor cover 100% of the costs associated with Subject Injury
- Sponsor provide a carve-out for Medicare, Medicaid and other governmental healthcare insurance
- Sponsor provides funding for Subject Injury only after what is not covered by Insurance
- Sponsor refuses to pay for Subject Injury



# Coverage Analysis

<b>IRB Number#</b>	<b>PAF#</b>
<b>NCT Number: NCT01958021</b>	
<b>Documents reviewed: Protocol, 9/20/13, Informed Consent, Draft Budget, Letter from Sponsor with IND number</b>	
<b>FDA Assigned IND number: 117,796</b>	Pending Submission
<b>FDA Assigned IDE number:</b>	N/A
<b>Is study a qualifying clinical trial under Medicare's Clinical Trial Policy?</b>	Yes

CT or MRI (chest, abd, pelvis) Whole body scan)	PS at screening,	L28516	See section 7.2 of study (CT or MRI (chest, abd, pelvis mandated) as is whole body bone scan)
PET Scan (whole body scan)	PS at screening	220.6	
PFT's	PS at screening	LCD L32762 (Novitas Soln)	No LCD in IL. This is not a screening test approved for coverage by Medicare; therefore in order to obtain coverage, the patient has to be symptomatic and the PI has to document medical necessity.
CT or MRI (chest, abd, pelvis) For subjects receiving study medications	N		Recist guideline version 1.1; NCCN v3.2013 Invasive Breast Cancer, PI to document medical necessity
PT or INR/ APTT	CL	NCD 190.16/190.17	Medicare has specific guidelines for indication

# Additional Information

- Advanced Beneficiary Notice (ABN) aka Beneficiary Notice Initiative (BNI)
- Pre-Certification/Pre-Determination? Pre-Authorization for commercial payors- get it in writing
- If errors in billing occur, easier to cure when discovered

# Ticklers

- Sponsor to provide device at no-cost; institution agrees to submit claims to third party payors= ?
- Sponsor shall pay for all reasonable medical expenses incurred for the necessary medical treatment of such injury which are not covered by subject's medical or hospital insurance or other governmental programs providing such service=?
- Anything that addresses Medicare/Medicaid or other governmental healthcare insurance=?

# Thank You

## Contact Information

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