

# Clinical Research Billing

*UC BRAID – September 2012*

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# Agenda

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## ▶ **Your Call**

- ▶ Skip 101/Informal Discussion re: UC BRAID Opportunities
- ▶ CRB 101 Presentation
- ▶ Open Q&A Forum (CRB and/or Other)

## ▶ **Billing Under Medicare NCD and SB 37**

- ▶ Basics
- ▶ When does a procedure qualify as a routine cost that can be billed to insurance?
- ▶ If we're billing the procedure to insurance, how can we convince the sponsor to pay for an injury arising from the procedure?



# Clinical Research Billing 101

# Medicare Reimbursement: Background

**MEDICARE**  **HEALTH INSURANCE**

1-800-MEDICARE (1-800-633-4227)

NAME OF BENEFICIARY  
**JANE DOE**

MEDICARE CLAIM NUMBER      SEX  
**000-00-0000-A**      **FEMALE**

IS ENTITLED TO      EFFECTIVE DATE  
**HOSPITAL (PART A)      07-01-1986**  
**MEDICAL (PART B)      07-01-1986**

SIGN HERE → Jane Doe

Medicare pays only if specified other sources of insurance are unavailable

- ▶ Medicare pays for health care items and services furnished to individuals eligible for Medicare coverage (“beneficiaries”) that:
  - ▶ Fall within a designated benefit category (e.g., hospital, ambulance, physician, laboratory)
  - ▶ Are not excluded from coverage by statute or through a national non-coverage decision (e.g., personal comfort items, cosmetic surgery, hearing aids)
  - ▶ Are reasonable and necessary for prevention (in specified cases), diagnosis, or treatment

# Some Relevant Medicare Coverage Rules

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- ▶ Under hospital reimbursement rules, when research is conducted in conjunction with, and as part of, the care of patients and associated costs are allowable costs
  - ▶ Costs incurred for research purposes over and above usual patient care are not allowable (e.g., extra patient care days must be treated as non-Medicare days)
  - ▶ Costs reimbursed by others are not allowable
  - ▶ Some studies on hospital administration/operations are fully allowable on the cost report
- ▶ CMS is barred from excluding coverage of routine costs associated with certain studies of Category A medical devices
- ▶ Medicare may cover healthcare items and services in other circumstances, including
  - ▶ Studies conducted pursuant to legislation enacted by Congress
  - ▶ Coverage with evidence development (“CED”) program studies
  - ▶ PCORI comparative effectiveness research contracts

# National Coverage Decision: Background

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- ▶ Before 2000, Medicare coverage policies were interpreted inconsistently by fiscal intermediaries (hospital contractors) and carriers (physician contractors) across the country
- ▶ Uncertainty contributed to under-representation of patients age 65 and older and uncertainty about the safety and effectiveness of tested interventions
- ▶ Congressional hearings and other initiatives eventually resulted in a presidential Executive Memorandum and, subsequently, the original iteration of the NCD
- ▶ NCD affects only “clinical trials,” which are not defined in the document

# Do You Need a Coverage Analysis?

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- ▶ Coverage Analysis Unnecessary
  - ▶ Data collection only (e.g., registry)
  - ▶ Observational only (e.g., comparative effectiveness where no procedures or interventions will be performed for study purposes but rather standard of care practices will be observed)
  - ▶ Retrospective/data analysis only (e.g., review of existing data from clinical care processes or other studies)
  - ▶ Beware other “exemptions” from coverage analyses – some may result in inappropriate charge handling
- ▶ Limited Coverage Analysis Necessary
  - ▶ Sponsor pays for everything
  - ▶ No sponsor/sponsor pays for nothing
- ▶ Note: Who Decides at Your Medical Center?

# Qualifying Clinical Trial

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1. Subject or purpose of study must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physician service, DME, diagnostic test)
2. Trial must not be designed exclusively to test toxicity or disease pathophysiology – must have therapeutic intent
3. Must enroll patients with diagnosed disease
  - ▶ No healthy volunteers in most cases
  - ▶ Studies of diagnostic interventions may enroll healthy patients to have a proper control group
4. Must exhibit seven desirable characteristics
  - ▶ CMS has not developed a self-certification process
  - ▶ Certain studies are deemed to exhibit the desirable characteristics

## Deemed Studies

- Funded by NIH, CDC, AHRQ, CMS, DOD, VA
- Supported by a cooperative group funded by above
- Conducted under an IND
- IND-exempt under 21 CFR 312.2(b)(1)



# Desirable Characteristics

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- ▶ The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
- ▶ The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
- ▶ The trial does not unjustifiably duplicate existing studies;
- ▶ The trial design is appropriate to answer the research question being asked in the trial;
- ▶ The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
- ▶ The trial is in compliance with Federal regulations relating to the protection of human subjects; and
- ▶ All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

# NCD on Desirable Characteristics

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- ▶ Clinical trials “should have” these characteristics
- ▶ AHRQ will convene a panel to develop verifiable and, where possible, dichotomous qualifying criteria that indicate a strong probability that the study exhibits the desirable characteristics
  - ▶ Trials that meet qualifying criteria will receive Medicare coverage of routine costs after lead PI certification to that effect
  - ▶ Process will require PI to enroll the study in a Medicare clinical trials registry still under development
  - ▶ Some trials are automatically qualified (see deemed categories above)
- ▶ Medicare will cover costs of qualifying trials that:
  - ▶ Are deemed to be automatically qualified
  - ▶ Are certified to meet the qualifying criteria
  - ▶ Misrepresentation may result in repayment obligations and fraud enforcement
- ▶ CMS/AHRQ never developed “qualifying criteria”

# Medicare Benefit Categories (Examples)

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- ▶ Ambulance
- ▶ Chiropractic
- ▶ Dental
- ▶ Diagnostic Tests
- ▶ Drugs and Biologicals
- ▶ Durable Medical Equipment ; Prosthetics, Orthotics, Supplies
- ▶ Extended Care Services (SNF)
- ▶ Home Health Services
- ▶ Hospice Care
- ▶ Hospital (Inpatient, Outpatient, Psychiatric, CAH)
- ▶ PT/OT/ST
- ▶ Physician, Non-Physician Practitioner
- ▶ Preventive, Screening Services\*

*Simple rule: if the subject or purpose of the study is evaluation of an item or service that normally would be billed to Medicare outside a trial, the study likely satisfies the “Medicare benefit category” condition.*

# Therapeutic Intent/Misconception

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- ▶ Determined based on purposes, objectives, endpoints
  - ▶ A study may have therapeutic intent even if its primary objective is not treatment of individual participants' disease
  - ▶ Therapeutic intent ideally should be expressly reflected in protocol discussion of purposes or objectives
- ▶ Some types of studies are unlikely to have therapeutic intent or are likely to be subject to particularly intense scrutiny
  - ▶ Pharmacokinetic studies recruiting healthy, normal volunteers
  - ▶ Mechanism of action studies
  - ▶ Phase I (safety) studies
- ▶ Implications of “therapeutic misconception” concerns
  - ▶ Presumption that research by definition has no therapeutic intent
  - ▶ Informed consent language expressly disclaiming any therapeutic intent

# Statutorily Excluded / Non-Coverage Determinations

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## Examples

- ▶ Cosmetic surgery
- ▶ Eyeglasses (in most cases); hearing aids
- ▶ Personal comfort items (note hospice exemption)
- ▶ Custodial care (note hospice exception)
- ▶ Most dental services

- ▶ Statutory
  - ▶ Definitions: 42 U.S.C. § 1395(x): <http://www.law.cornell.edu/uscode/text/42/1395x>
  - ▶ Excluded Services 42 U.S.C. § 1395(y): <http://www.law.cornell.edu/uscode/text/42/1395y>
- ▶ CMS Manuals and Coverage Information
  - ▶ Medicare Coverage Center: <http://www.cms.gov/Medicare/Coverage/CoverageGenInfo/index.html>
  - ▶ Northern California: <http://go.cms.gov/JCpKli>
  - ▶ Southern California: <http://go.cms.gov/IR1jWU>
- ▶ Palmetto
  - ▶ Part A (Facility): <http://bit.ly/IZANjk>
  - ▶ Part B (Professional): <http://bit.ly/KZdZLp>

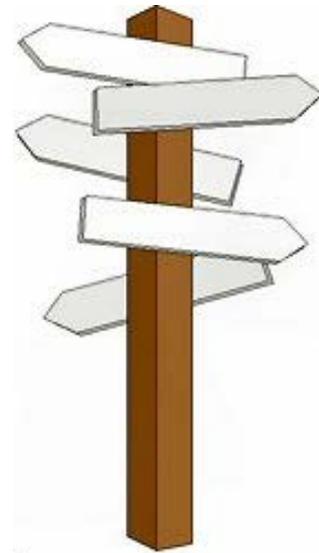


Palmetto GBA.  
PARTNERS IN EXCELLENCE.

# Alternatives for Non-Qualifying Trials

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- ▶ Revert to coverage rules outside the NCD
  - ▶ Note on need for consistent policy within a medical center (and preferably systemwide)
  - ▶ Note on implications for coding and billing process (v70.7 plus Q1 serves as an attestation that the item or service is routine patient care or treatment of injuries arising from participation in a Medicare-covered clinical trial)
- ▶ Pursue a local coverage determination (“LCD”) from Palmetto, California’s local Medicare Administrative Contractor (“MAC”)
- ▶ Consider self-certification approach
  - ▶ Note on need for consistent policy approach (and global vs. case-by-case policies)



# Only Some Costs of Care Are Covered

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## Covered

- ▶ Conventional care
  - ▶ I/S typically provided absent a clinical trial
- ▶ Administration
  - ▶ I/S required solely for provision of the investigational I/S
  - ▶ I/S required for clinically appropriate monitoring of effects or prevention of complications
- ▶ Complications/Injuries
  - ▶ I/S required for diagnosis and treatment

## Not Covered

- ▶ Investigational item/service itself (unless otherwise covered outside the study)
- ▶ I/S provided solely to satisfy data collection and analysis needs and not used in direct clinical management
- ▶ I/S customarily provided by sponsor free of charge for any enrollee

# (Medicare) Coverage Analysis

# Multiple Processes



*Note: to avoid confusion and potential compliance risk, all study-related documents should be consistent (grant/contract documents including budget, investigator's brochure/protocol, IRB application, informed consent document, study calendar).*

1. Determine whether a coverage analysis is required
2. Complete basic coverage analysis
3. Identify all healthcare items and services that could generate a charge at a UC medical center
4. Determine which will generally be covered by Medicare (and other major payers) – *work with departmental billing staff*
5. Negotiate budget with sponsor (scheduled/protocol-required items and services)
  - ▶ All non-covered items and services (if no sponsor, identify internal source of payment)
  - ▶ Non-clinical items and services (e.g., study administration and coordination, IDS set-up, IRB/regulatory fees, etc.)
  - ▶ Unscheduled items and services
6. Communicate budget to **billing process, to facilitate segregation of charges to research/bulk account or insurance; and to assure appropriate coding**



# Budget/Schedule of Events

- ▶ When healthcare items and services are conflated with administration/coordination activities, confusion can arise as to appropriate handling.
- ▶ CTA budgets ideally should clearly:
  - ▶ Distinguish between those events that can generate a charge in the medical center's billing system and those events that cannot
  - ▶ Clearly identify the circumstances when the sponsor is paying (or not paying) for items and services that could generate a charge
- ▶ Unscheduled items and services
  - ▶ CTA budgets cannot address with specificity how to handle payment for diagnosis and treatment of complications
  - ▶ Can address in general terms (e.g., rate at which payment will be made if I/S are provided at UC)

# Coding Instructions for the Billing Process

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- ▶ What charges should be directed to the patient account (insurance or self-pay) and what charges should be directed to the bulk account (sponsor or institution)
- ▶ For charges directed to patient account:
  - ▶ Whether to code with v70.7
  - ▶ Which protocol-required items and services are investigational (those being investigated as an objective within a study, whether approved, unapproved, covered, or not covered outside the study), requiring a Q0 modifier
  - ▶ Which protocol-required items and services are routine (covered for beneficiaries outside the study; used for direct patient management; not investigational)
- ▶ Who is participating on a study (in order to flag emergency and other unscheduled charges that may be related to a study and require special handling)

# Special Circumstances

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- ▶ No sponsor/sponsor pays for nothing
  - ▶ Assure all items and services that can generate a charge to the patient account qualify as routine costs
  - ▶ Communicate to the billing process which items and services require CRB coding and what codes are appropriate (e.g., Q0 or Q1 for any given item or service) ... this may require a billing grid or calendar
- ▶ Sponsor provides only study drug or device
  - ▶ See above
  - ▶ Drug/device administration charges may require special handling (no charge/nominal charge reflected to avoid denial of administration charges)

# Hypothetical 1

Procedures	Pre-Screen	Screen	Visit 1	Visit 2
Inclusion/Exclusion Criteria	X			
Gene Expression Analysis	X			
Informed Consent	X			
H&P		X	X	
Chest X-Ray		X		
Concomitant Meds	X	X	X	X
QOL		X		X
CBC	X			X
Adverse Events				X
Pharmacy	X (set-up)		X (dispense)	
Physician Investigator	X	X	X	X
Study Coordinator	X	X	X	X
TOTAL	\$	\$	\$	\$

# Hypothetical 2

Procedures	Pre-Screen	Screen	Visit 1	Visit 2
Inclusion/Exclusion Criteria	\$			
Gene Expression Analysis	\$			
Informed Consent	\$			
H&P		\$	\$	
Chest X-Ray		\$		
Concomitant Meds	\$	\$	\$	\$
QOL		\$		\$
CBC	\$			\$
Adverse Events				\$
Non-Procedures				
Pharmacy Dispense			\$	
Physician Investigator	\$	\$	\$	\$
Study Coordinator	\$	\$	\$	\$
TOTAL	\$	\$	\$	\$

# Hypothetical 3

Clinical Activities	Pre-Screen	Screen	Visit 1	Visit 2
Office Visit	SOC	SOC	SOC	SOC
Blood Draw & CBC	SOC	S (\$)		SOC
Chest X-Ray		S (\$)	SOC	
Drug			S	
Drug Administration			SOC	
SPONSOR PYMT TOTAL	N/C	\$	N/C	N/C
Research Activities				
Inclusion/Exclusion Criteria	X			
Gene Expression Analysis	X			
Informed Consent	X			
Concomitant Meds	X	X	X	X
QOL		X		X
Adverse Events				X
Pharmacy	X		X	
Physician Investigator Fee	\$	\$	\$	\$
Study Coordinator Fee	\$	\$	\$	\$
SPONSOR PYMT TOTAL	\$	\$	\$	\$

▶ **OGC – Health Law Team:**

<http://www.ucop.edu/ogc/practgrps.html#health>

▶ **Health Sciences Compliance:**

<http://www.universityofcalifornia.edu/compaudit/hlthscicomp/>

**Questions**

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