

Medicare Coverage and Clinical Trials

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Agenda

- What Medicare will and won't cover in a clinical research trial
- How to conduct a Medicare Coverage Analysis
- Coding and documentation requirements
- Your role in conducting a fiscally compliant clinical research trial

MEDICARE OVERVIEW

Key Points

- Medicare is administered by the Center for Medicare and Medicaid Services (CMS)
- Medicare decisions are simply payment determinations, not judgments or guidelines on clinical practice.

Medicare Coverage

Medicare may cover two types of items and services:

1. those that are reasonable and necessary to treat an illness or injury; and
2. a limited number of preventative care services (e.g. annual mammogram)

Medicare May Cover...

- Items and services typically provided absent clinical trial (medically necessary standard of care)
- Items or services required solely for the provision of the investigational item or service (e.g. admin of chemo drug)
- Reasonable and necessary items and services used to diagnose, treat, and prevent complications.

Medicare Does NOT Cover...

- Investigational item or service itself
- Items and services *not* used in the clinical management of the patient
 - Data collection above and beyond Standard of Care
 - Pre-study eligibility screening

Also not covered...

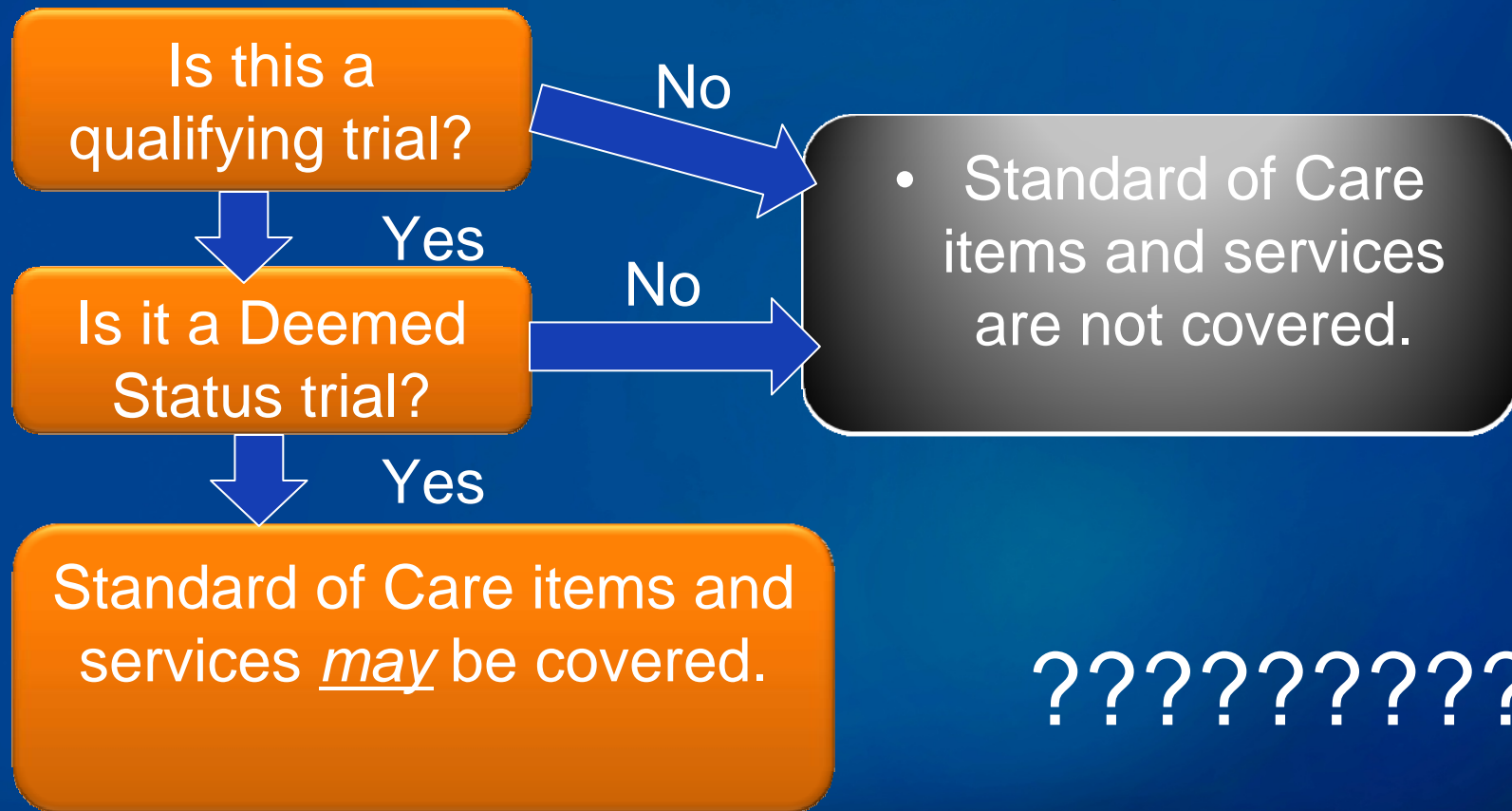
- Items and services customarily provided by the research sponsor free of charge
- Items and services for which there is no Medicare benefit category
- Items and services statutorily excluded from Medicare coverage
- Items promised free in the Informed Consent

Medicare Secondary Payor Rule (MSP)

- As a general rule, CMS is the secondary payor, when possible.
- If another funding source, including sponsors, covers *or offers to cover* an item or service, Medicare cannot be billed.
- When policies conflict (e.g. insurance, state or sponsor policy) federal law wins.

MEDICARE COVERAGE OF INVESTIGATIONAL DRUG TRIALS

Medicare's NCD and Investigational Drug Trials



Does my trial qualify?

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category.
- The trial must have therapeutic intent.
- Trials must enroll patients with a diagnosed disease. Trials of diagnostic intervention may enroll healthy patients in order to have a proper control group.

CMS's requirements

- Trial must meet the 7 Desirable Characteristics
- Trial must be “Deemed” as Automatically Qualified
 - What does that mean???

CMS's Deemed Trials

- Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA
- Trials supported by centers or cooperative groups that are funded by above-mentioned agencies.
- Trials conducted under an Investigational New Drug application (IND) reviewed by the FDA
- Trials that are exempt from having an IND under 21 CFR 312.2(b)(1)

My trial qualifies. Now what?

- Review types of goods and services that may be covered (slides 5 through 8).
- Conduct a Medicare Coverage Analysis (MCA) to document eligibility.
- Separate Standard of Care (SOC) items and services from Research.
- Document SOC vs. Research and incorporate in study budget.

MEDICARE COVERAGE OF INVESTIGATIONAL DEVICES

Category A vs. B

- A = A novel or innovative experimental device for which the absolute risk of the device type has not been established and initial questions of safety and effectiveness have not been resolved.
- B = Devices that are new generations of proven technologies. Initial safety questions have been resolved. Evolutionary changes in proven technology.

Coverage Principles Summary

Category A	Category B
•Trials involving immediately life-threatening conditions	•All trials
•Device NOT covered	•Device covered
•Standard of Care services covered	•Services “related to” device covered
•Medicare contractor approval required	•Medicare contractor approval required

At UK, contact Elaine Younce in Managed Care Finance
http://www.mc.uky.edu/ukcro/fiscal_man_page.htm#SCDS

Category A Devices

- Covered under MMA effective January 1, 2005
 - If used before 2010, device must be used to diagnose, monitor, or treat an immediate life-threatening disease or condition.
 - “life-threatening” = a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months, or in which premature death is likely without early treatment.

Category B Devices

- Covered since 1995 under The Device Regulation (42 CFR Part 405 and 411)
- Medicare will cover the investigational device itself, as well as related services
- Payment may not exceed what Medicare would pay for a comparable device

Coverage of Category B

- Coverage determination must be made before any claims are submitted.
- Medicare device coverage decisions are processed through UK Managed Care Finance AND KMSF-you must have BOTH
 - UK = Elaine Younce 257-9521
 - KMSF = Marcia Atwell 257-7910 ext. 252

CONDUCTING A MEDICARE COVERAGES ANALYSIS (MCA)

Why should I do an MCA?

- Designate charges to the appropriate payor
- Design and evaluate study budget
- Delineate subject financial risk
- Document due diligence

The Four “D’s”

Do it Two Times

1. Initial MCA should be conducted parallel with development of study budget
2. Final MCA should be conducted once all study documents final

The Tools

- Instruction Sheet
- MCA Coverage Form
- Standard of Care vs. Research Form
- CRO web site
(http://www.mc.uky.edu/ukcro/fiscal_man_page.htm)

CODING FOR DRUG TRIALS

Medicare Part A – Hospital

- Specified inpatient hospital services
- Post hospital skilled nursing care
- Home health services
- Hospice care for aged and disabled individuals
 - Billed through Medicare Fiscal Intermediary (FI)

Medicare Part B - Professional

- Doctor's services
- Outpatient hospital care
- Durable medical equipment
- Some medical services not covered by Part A
 - Billed through Medicare Carrier

Requirements for Billing Medicare

- May include the use of
 - V70.7 ICD-9 diagnosis code
 - Procedure code modifier
 - Condition code
 - Revenue code
 - IDE number
 - 8-digit study number
 - Additional items in medical record

Addition Items in Record

- Trial name
- Sponsor
- Sponsor-assigned protocol number
- Copy of the signed informed consent document

CODING FOR CATEGORY A DEVICES

Category A Device Requirements

- Q0 modifier
- Condition code 30
- V70.7 diagnosis code
- IDE number
- Related HCPCS code
- Revenue code 624
- 8-digit study number

Part A vs. Part B

Billing Medicare for Category A Devices	
Medicare Part A (Fiscal Intermediary)	Medicare Part B (Medicare Carrier)
Condition code 30 for all types of services	
ICD-9 Diagnosis code V70.7 (secondary)	ICD-9 Diagnosis code (not required)
Q0 modifier	Q0 modifier

CODING FOR CATEGORY B DEVICES

Category B Device Requirements

- IDE number (also include in Medical Record)
- Related HCPCS code from CMS contractor
- Revenue code 0624
- 8-digit study number

CODING FOR HEALTHY VOLUNTEERS

Health Volunteer – Part A

- Condition Code 30
- Diagnosis code V70.7 is reported as the *secondary* diagnosis
- Q1 Modifier

Healthy Volunteer – Part B

- Report Q1 at the line-item level
- Diagnosis code V70.7 is reported as the *primary* diagnosis

Healthy Volunteer Differences

Billing Medicare Part A and Part B	
Medicare Part A (Fiscal Intermediary)	Medicare Part B (Medicare Carrier)
Condition code 30 (for all types of services)	
ICD-90 Diagnosis code V70.7 (as secondary diagnosis for all types of services)	ICD-9 Diagnosis code V70.7 (primary diagnosis)
Q1 modifier	Q1 modifier

Your Role as Coordinator

- Due Diligence
- Document
- Know who to contact with questions
 - UKCRO
 - PI
 - Department Administrators and Coders
 - Office of Corporate Compliance

For More Information

http://www.mc.uky.edu/ukcro/fiscal_man_page.htm



For phone numbers, names and who does what

OR

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