Clinical Research Billing & Compliance

SESSION 1:

Does a study need a coverage analysis and is the study qualifying?

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IS THE STUDY QUALIFYING AND DOES IT NEED A COVERAGE ANALYSIS?

Medicare Basics and History

Why Does it Matter?

Do I need a coverage analysis?

What is a Qualifying Clinical Trial?

MEDICARE BASICS

Established by Congress in 1965 as part of the Social Security Act.

June 7, 2000 – President Clinton issued an executive memorandum directing the Medicare program to cover certain services during clinical research.

September 19, 2000 – National Coverage Determination 310.1 was issued

July 2006 – CMS began its first reconsideration for NCD 310.1

July 9, 2007 – CMS made small revisions to NCD 310.1

NATIONAL COVERAGE DETERMINATION 310.1

NCD 310.1 has two official names:

> "National Coverage Determination for Routine Costs in Clinical Trials"

> "Clinical Trials Policy"

The policy offers Medicare coverage for certain types of clinical research studies and not just when there is a test article.

THE STARTING WORDS OF NCD 310.1

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.

Important Statutory Basis for Coverage

Medicare covers items and services that are "reasonable and necessary to diagnose or treat illness or injury."

This rule never goes away –

It's in the context in which NCD 310.1 is written

It is also why NCD 310.1 also states "All other Medicare rules apply."

NCD 310.1

CMS implemented its Clinical Trial Policy through the National Coverage Determination (NCD) process.

Prior to Medicare's NCD 310.1, beneficiaries did not have guaranteed coverage to clinical research studies.

While the Clinical Trial Policy only applies to clinical research services provided to Medicare beneficiaries and is specifically written for only a sub-set of research studies (government funded studies and drug studies) it nevertheless contains the most advanced framework for analyzing clinical research services for reimbursement.

ROUTINE COSTS IN CLINICAL TRIALS

Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials except when:

The Sponsor pays for the item or service, or promised to pay

The service is promised at no cost to the patient in the ICF

The service is not covered by Medicare outside of a study

COVERAGE ANALYSIS

Basically comes down to one thing:

What can or can't I bill to insurance during a clinical trial?

Types of studies that may not require a coverage analysis

The study is only reviewing retrospective and prospective patient charts and patient medical records.

*Resident/medical student research

*Nursing research

The study consists of non-billable procedures(ie., interviews, questionnaires, surveys, QOL studies)

*No items that have a CPT code within the study calendar

Observational study

*There is no investigational item or service

*The study is comparing two approved items/services to see if one has better results than the other

*Registry/data collection after an item/service has been performed to observe outcomes.

*If there is nothing investigational or experimental, and all services are conventional care, the services are to be billed as normal. All Medicare rules apply.

Types of studies that may not require a coverage analysis

IRB exempt Study

*DHHS regulations in 45 CFR 46.101 outlines categories of minimal risk research as being exempt from the federal policy for the protection of human subjects.

*The study must be submitted to the IRB for review and if approved, they will send an exempt certification letter.

Compassionate use (Expanded Access) Study

*Studies that refer to the use of an IND outside of a clinical trial by people with serious life-threatening conditions who do not meet the enrollment criteria for the clinical trial in progress.

*These studies are not considered research, although they do still require IRB approval.

Why??

1. Potential Overpayment-Double billing
2. Fines and penalties
3. Better budgeting
4. Financial viability of a research study
5. Patient satisfaction

Qualifying Clinical Trial

2 Part Test:

Part 1 – Is the study "deemed to have the 7 desirable characteristics?

Part 2 – Does the study have all 3 necessary requirements?

SUMMARY FOR DETERMINING A QUALIFYING TRIAL

Must be ONE of 4 types of trials deemed to meet 7 desirable characteristics

ONE of these MUST BE TRUE	Funded by NIH, CDC, AHRQ, CMS, DOD or VA	Supported by center or cooperative group funded by NIH, CDC, AHRQ, CMS, DOD or VA	Conducted under an investigational new drug application (IND)reviewed by the FDA	IND exempt under 21 CFR 312.2(b)(1)

ALL OF THESE MUST BE TRUE

Evaluate an item or service that falls within a Medicare benefit category.

Have therapeutic intent

Enroll patients with diagnosed disease

• Medicare Benefit Category

Medicare Benefit Category Resource Document

NCD 310.1 states:

"The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids)."

Medicare Benefit Categories Listed in NCD 310.1

1. Ambulance Services
2. Ambulatory Surgical Center Facility Services
3. Antigens
4. Artificial Legs, Arms, and Eyes
5. Audiology Services
6. Blood Clotting Factors for Hemophilia Patients
7. Bone Mass Measurement
8. Certified Nurse-Midwife Services
9. Certified Registered Nurse Anesthetist Services
10. Chiropractor Services
11. Clinical Nurse Specialist Services
12. Clinical Social Worker Services
13. Colorectal Cancer Screening Tests
14. Comprehensive Outpatient Rehabilitation Facility (CORF) Services
15. Critical Access Hospital Services
16. Dentist Services
17. Diabetes Outpatient Self-Management Training
18. Diagnostic Laboratory Tests
19. Diagnostic Services in Outpatient Hospital
20. Diagnostic Tests (other)
21. Diagnostic X-Ray Tests
22. Drugs and Biologicals
23. Durable Medical Equipment
24. Erythropoietin for Dialysis Patients
25. Extended Care Services
26. Eyeglasses After Cataract Surgery
27. Federally Qualified Health Center Services
28. Hepatitis B Vaccine and Administration
29. Home Dialysis Supplies and Equipment
30. Home Health Services
31. Hospice Care
32. Immunosuppressive Drugs
33. Incident to a physician's professional Service
34. Influenza Vaccine and Administration
35. Inpatient Hospital Services
36. Inpatient Psychiatric Hospital Services
37. Institutional Dialysis Services and Supplies
38. Leg, Arm, Back, and Neck Braces (orthotics)
39. Medical Nutrition Therapy Services
40. Nurse Practitioner Services
41. Optometrist Services
42. Oral Anticancer Drugs
43. Oral Antiemetic Drugs
44. Orthotics and Prosthetics
45. Osteoporosis Drug
46. Outpatient Hospital Services Incident to a Physician's Service
47. Outpatient Occupational Therapy Services
48. Outpatient Physical Therapy Services
49. Outpatient Speech Language Pathology Services
50. Partial Hospitalization Services
51. Physician Assistant Services
52. Physicians' Services
53. Pneumococcal Vaccine and Administration
54. Podiatrist Services
55. Post-Hospital Extended Care Services
56. Post-Institutional Home Health Services
57. Prostate Cancer Screening Tests
58. Prosthetic Devices
59. Qualified Psychologist Services
60. Religious NonMedical Health Care Institution
61. Rural Health Clinic Services
62. Screening for Glaucoma
63. Screening Mammography
64. Screening Pap Smear
65. Screening Pelvic Exam
66. Self-Care Home Dialysis Support Services
67. Shoes for Patients with Diabetes
68. Skilled Nursing Facility
69. Splints, Casts, Other Devices Used for Reduction of Fractures and Dislocations
70. Surgical Dressings
71. Transplantation Services for ESRD-Entitled Beneficiaries
72. X-ray, Radium, and Radioactive Isotope Therapy

Important CMS Note in NCD 310.1:

"This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service."

Diagnosed Disease

*Inclusion criteria require specific disease or medical conditions.

Examples:

Histological or cytological confirmed breast cancer

Clinical signs consistent with a stroke

*Health volunteers may be enrolled for a control group in diagnostic intervention studies.

*Cite from the Inclusion Criteria section of the Protocol.

What is Therapeutic Intent?

*To have therapeutic intent a study must be designed to intervene in a patient's condition to help the patient.

*NCD 310.1: "The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent."

*NCD 310.1 does not clearly discuss what is sufficient therapeutic intent.

***"An appropriate definition would be that a qualified trial exhibits therapeutic intent when a MAJOR OBJECTIVE OF THE STUDY seeks as its goal the diagnosis or treatment of disease including observation of benefit of the intervention under study. While this does not require that the primary objective of the trial be one of therapeutic intent, therapeutic intent must be of sufficient importance to the outcome of the study. We propose to define sufficient importance to the outcome of the study to mean that the study has appropriate statistical power and planned analyses to ensure that the findings will substantially enhance the scientific knowledge base on the impact of the intervention under study on health outcomes."**

-CMS's Clinical Trial Policy Medicare Coverage Advisory Committee Questions, December 13, 2006

Putting that into practice

*Patients require therapeutic intervention – is the study trying to improve their condition or health.

*The study cannot solely be conducted to assess toxicity or adverse events. These are considered scientific outcomes, not therapeutic outcomes.

*Areas of the protocol to pay special attention to:

Study Objectives-purpose and goals of the study

Endpoints-desired results

Study Design

Language to look for

*Anchor your reasoning to therapeutic outcomes.

Assess anti-cancer activity

Compare progression free survival

Evaluate the efficacy of treatment

*Language related to the study drug which is not therapeutic intent:

Evaluate the safety and tolerability

Assess the pharmacokinetics

*It is difficult to find therapeutic intent in Phase I clinical trials.

Phase I drug studies are typically designed to test the toxicity of a drug.

*Phase I/II studies-quote reasoning from both parts of the protocol when assessing therapeutic intent.

The QCT Analysis Process

Question	Yes	No	Comment
Deemed Study?			
Item or service falls within a benefit category?			
Enrolls subject with diagnosed disease?			
Study designed with therapeutic intent?			
Qualifying Clinical Trial?			

Does the Study need a Coverage Analysis?

A Phase I study enrolls subjects with solid tumors to study the off-label combination of Drug A and Drug B. The subjects receive CT or MRI Images monthly and a variety of lab tests three times per week.

A Phase 2 study enrolls subjects with early dementia to study an unapproved drug. The study lasts for 24 months and requires numerous physical exams, neurological exam, MRIs, lab tests, and psychological exams. The sponsor is paying for every protocol required service.

A research study enrolls subjects after a kidney transplant which requires the subject to record for three months diary answers to questions twice per day regarding pain, mobility, and social interactions with family.

A Phase 3 study enrolls subjects with soft-tissue sarcoma to study a chemotherapy agent that has never been approved. The sponsor provides the drug without charge.

QUESTIONS?