Coverage Analysis | CA

?MISSION

To provide comprehensive coverage analysis and budgeting services for researchers and administrators to enhance their ability to achieve excellence in clinical research while adhering to University, Federal, and State guidelines to ensure billing compliance.

WHAT IS A COVERAGE ANALYSIS

A coverage analysis (CA) identifies the financial accountability for each item or service in a clinical trial. It is an in-depth review of clinical trial documents, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and published practice guidelines to determine the Medicare billing status of items and services that are documented in the research protocol. As a result, services will be appropriately billed to a third party payor (e.g., Medicare, private insurance, or the patient), the trial sponsor, the study grant or other funding source.

All studies involving human research subjects require a review for coverage analysis. A CA is required to use Medical Center resources and facilities. There are some scenarios where a CA is not required, such as studies only reviewing medical records.

Coverage Analysis Review Objectives

1. Identify whether a study is a Qualifying Clinical Trial (QCT) that allows for billing certain study items/services to insurance pursuant to applicable laws and regulations; and
2. Determine billing designations for all patient care costs required by the study. Billing designations for study required items/services may either be:
    - Routine Costs that may be billed to a study participant and/or their insurer(s); or
    - Study Costs for items/services that are primarily required for research purposes that should be funded by the respective study sponsor and/or internal study account.

How Routine Costs are Determined

The Centers for Medicare & Medicaid Services (CMS) provide guidance to help differentiate Routine Costs from Study Costs. National and Local Coverage Determinations, professional medical association guidance, and nationally recognized peer-reviewed publications are often utilized as resources to support Coverage Analysis billing designations.

The first step in Coverage Analysis is to determine if the study qualifies. It is a process for Principal Investigators to attest to Medicare that a clinical study meets certain Medicare qualifying criteria. When the study meets this criterion, it

is a "qualifying clinical trial." This means that Medicare (and by extension, other insurance companies) will cover associated routine and expanded patient care during the clinical study. Routine care is also called "conventional care" and defines procedures/ services that would be performed absent a clinical study. Expanded care includes additional services such as clinically necessary monitoring of the effects the investigational drug or device, administration of the clinical study article (drug or device), procedures for prevention, diagnosing, and treatment of side effects or complications resulting from the patient's participation in the clinical study (Medicare Clinical Trial Policy, NCD 310.1).

Medicare will not cover items and services that are paid for by the sponsor, promised free in the informed consent document, not ordinarily covered by Medicare, and studies that are solely for data collection or analysis.

What types of services are covered in a clinical trial?	
Qualified Trial	**Non-Qualified Trial**
Conventional or Standard of care (SOC)	Conventional or Standard of care (SOC)
Services to monitor effects of investigational drug/device	N/A
Services to administer investigational drug/ device (e.g., infusions, surgery)	N/A
Services to prevent, diagnose, and treat complications	Treatment of complications
Protocol related services and items must be billed with clinical trial modifiers and diagnosis codes for Medicare patients	Services and items must **not** be billed with clinical trial modifiers

Last updated: 18 Sep 2019

Office Of Coverage Analysis Administration | OCAA

BENEFITS OF THE COVERAGE ANALYSIS

A coverage analysis ensures clinical research billing is compliant by Medicare standards, provides transparent clinical research transactions to prevent billing errors, and may be used as a tool to estimate costs and negotiate study budgets.

HOW IS A COVERAGE ANALYSIS INITIATED AND WHO COMPLETES THE REVIEW

A project submission to the Human Research Protection Program (HRPP) triggers an automated notification to OCAA for coverage analysis review. OCAA comprises a team of analysts who specialize in Medicare policies and healthcare guidelines. The analysts work closely with the Principal Investigators (PI's) and their study teams to review and finalize the coverage analysis.

BUDGETING SERVICES

OCAA now offers budgeting services for industry initiated clinical trials. With the increasing costs and demand of clinical trials, our team offers full concierge services to execute your study budgets and to enhance your experience with the study sponsor. We will develop a detailed budget and negotiate the figures with the sponsor to ensure the sponsor covers the full cost of conducting the study at UCSD.

WHAT YOU CAN EXPECT FROM OUR BUDGETING SERVICE

Customer Service: We keep the PI apprised of the budget at all stages of the process. We offer in-person meetings to review our budgets to ensure the PI's input and budget goals are incorporated in our budgets. Each budget will be assigned an experienced analyst that will be your main point of contact should you need any clarification. Our analysts will be available via phone, email or in-person meetings to ensure the budget meets your needs.

Comprehensive Reviews: We capture all of the costs of conducting the clinical trial. In our budget development process we identify and budget for all costs from the beginning with study start-up costs all the way through to study close out costs, direct and indirect costs, per patient costs, personnel costs, invoice costs, supplies/equipment and facility costs, and central office fees.

Competitive Timelines: Our review and first draft of the budget will be sent out to the sponsor within 4 - 6 weeks of receiving the budget request through ePD.

Quality: After the study has started, we will follow up with your team for feedback. In the event the budget provided to you does not capture the appropriate costs we will renegotiate the budget with the sponsor.

WHAT IS THE COST OF THE BUDGETING SERVICE

For NEW studies: $3,250 (Inclusive of OH)

For AMENDMENTS to existing studies: $1,300 (Inclusive of OH)

HOW TO REQUEST OUR BUDGETING SERVICE

For NEW studies submit through ePD.

For AMENDMENTS to existing studies submit through the OCTA Application.

CONTACT US

For general inquiries please contact us at: ocaa@ucsd.edu or 858-534-4761

Titles:

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Device study Coverage Requirements

Investigators participating in an Investigational Device Exemption (IDE) Study that plans to request reimbursement for study procedures and materials from Medicare or third-party payers must ensure the following:

1. CMS IDE study coverage has been approved by CMS or local Medicare contractor
    - CMS approval of coverage for Category A devices applies to the routine care items and services required by the study, but not the experimental device
    - CMS approval of coverage for Category B devices allows for coverage of the routine care items and services required by the study as well as the investigational device.
2. Other devices that may be covered by Medicare include
    1. Premarket Approval (PMA)
    2. Humanitarian Device Exemption (HDE)
    3. 510(k) approved devices
    4. IRB-approved Non-Significant Risk (NSR) device

Drugs Study Coverage Requirements

Medicare will cover the cost of QCTs that are conducted under an Investigation New Drug (IND) reviewed by the FDA. IND exempt studies are deemed automatically qualified for coverage until further qualifying criteria are available. Once the qualifying criteria are available, the Principal Investigators of the study must certify that the study meets all qualifying criteria for Medicare coverage of routine costs. The new qualification will apply to the prospective study charges generated.

Please click here for more contact information.

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