PURPOSE

Establish a consistent comprehensive coverage analysis process that is well defined and performed on every clinical trial.

UCSF REQUIREMENT

Effective 6/1/2013, a formal coverage analysis must be completed in the OnCore system (Clinical Trial Management System) on every clinical research study that includes a medical procedure or service (e.g. blood draw, x-ray, biopsy, etc.) before any subjects are enrolled.

Units authorized to perform a formal coverage analysis are: the Clinical Trials Business Support Center (CTBSC), Investigational Trial Resource (ITR) or Division of Cardiology.

DEFINITION

A formal coverage analysis is a systematic review of all clinical research items, services, procedures, and documents along with relevant Federal and State medical billing regulations and policies (e.g. Medicare) to determine the appropriate funding source for each item or service.

COVERAGE ANALYSIS (CA) PROCESS

A CA must be completed prior to enrolling study subjects to verify the study information and billing plan.

In order to bill any entity besides the Sponsor for routine care costs of items and services, a clinical trial must meet certain criteria to qualify for reimbursement.

UCSF applies the Medicare National Coverage Determination for Routine Costs in Clinical Trials (NCD 310.1) to make this determination.

- Determine whether the study is a qualifying clinical trial (QCT)
  - Does the investigational item/service fall within a Medicare benefit category?
  - Is the trial designed with therapeutic intent?
  - Does the trial enroll patients with diagnosed disease? (e.g. inclusion criteria)
  - Is the study deemed to meet the 7 desirable characteristics?
  - Notate outcome of “deemed” status review
- Identify the investigational item or service
  - Verify FDA regulation status
• Determine whether the investigational item or service is billable
  o Verify service location and provider
  o Verify the NCT number (National Clinical Trial #)
  o Verify medical policy coverage (NCD/LCDs, published medical policies)

• Determine whether items and services listed in the protocol are billable
  o Verify service location and provider, as applicable
  o Note potential complications of the investigational item/service and verify medical policy coverage (NCD/LCDs, published medical policies)

• Analyze sponsor’s budget and payment terms
  o Verify items and services the sponsor has agreed to pay and/or provide
  o Verify that rates paid by the sponsor are higher than Medicare rates and less than the full retail rate for services performed in the Medical Center facility

• Assign a billing determination for every item and service listed in the protocol in the form of a study calendar in OnCore
  o Every item/service must be noted with a billing determination,
    ▪ **R** to indicate the service or procedure is a billable event to the research study and will not be billed to third party insurance
    ▪ **S** for each service or billable event which (a) is medically necessary for the patient’s care, (b) would have been incurred in the absence of the study (c) is a covered benefit/service and (d) will be billed to the patient’s insurance or patient’s account
    ▪ **NA** to indicate a bundled service or not a separately billable event
    ▪ **NB** as not billable, such as a device provided at no cost to UCSF from the sponsor

• Documents supporting routine care justification must be included as an upload in OnCore or listed under the OnCore CA comments for each procedure or service
  o Acceptable documentation for justification;
    ▪ Copies of medical coverage policies (e.g. NCD/LCD, etc.)
STANDARD OPERATING PROCEDURE
FORMAL COVERAGE ANALYSIS

- Routine care guidelines (e.g. NCCN, Up-To-Date, medical textbook excerpts, etc.)
- Link may be cited

- Compare case report forms to trial eligibility criteria, for accuracy
- Review the informed consent form (ICF) for appropriate cost language
- Validate consistency among study records by database and document comparison including the following:
  - Clinical trial agreement (CTA) budget and payment terms
  - Protocol and informed consent form(s) OnCore, IRiS, (and APeX databases for UCSF Medical Center services)
- Submit the completed CA to Principal Investigator for approval
  - Sign-off can be obtained in the following methods
    - Original signature on formal CA document
    - Email from PI email address, in email note the CT# and approval of completed CA with version date and approval date clearly noted
  - Original signed approval documents must be retained, per UCSF Record Retention Policy
  - Upon receipt of PI signed approval:
    - Click the “CA complete” button in OnCore
      - upload formal completed CA into Cactus system or input CA data in CACTAS system
      - CTBSC - PI or designee is required to confirm the agreement in OnCore
      - ITR- Notify Budget Manager and PPM CA status is complete

Examples of routine costs in a clinical trial

- Items or services that are typically provided absent a clinical trial (i.e. conventional care)
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service - in particular, for the diagnosis or treatment of complications
CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS)

OnCore is the system of record for formal coverage analysis of clinical trials at UCSF. Study calendars are configured and billing designations are assigned in OnCore for each protocol. Coverage analysis documentation is uploaded to OnCore and will include the final protocol with IRB-approved informed consent(s) and related manuals (e.g. Laboratory, Radiology, etc.), clinical trial agreement (CTA), and supporting justification for all billing determinations.

RESPONSIBILITY FOR PRINCIPAL INVESTIGATOR

It is the responsibility of the Principal Investigator (PI) to ensure that clinical services are billed appropriately and in compliance with relevant laws, regulations, UC policies, and contractual obligations.

INVESTIGATIONAL DEVICE EXEMPTION (IDE) PRE-APPROVAL PROCESS

Upon determining that a clinical trial is a qualifying clinical trial (QCT):

- Document the name of the investigational device and obtain a narrative description. Include a statement as to the devices similarities and differences from other products if not explicitly and clearly indicated in submitted documents.
- Obtain a copy of the final FDA approval letter(s) issued to provider, sponsor and/or device manufacturer.
- Obtain a copy of the Institutional Review Board (IRB) approval letter.
- Obtain a written description of the action(s) taken to conform to any applicable FDA and/or IRB special controls and/or other requirements.
- Obtain a copy of the clinical trial protocol and patient inclusion criteria.
- Obtain a copy of the IRB-approved, informed consent form(s) (ICF)
  - Validate the ICF financial responsibility section clearly indicates between the patient and sponsor liability, as applicable.
- Obtain a written description* of study team’s protocol for obtaining informed consent.
- Obtain coding that will be used to describe the service, procedure and device, on a claim.
- Complete and include the Noridian checklist for an IDE pre-approval packet submission.
- Email all required documents, (as attachments), to: iderequests@noridian.com
STANDARD OPERATING PROCEDURE
FORMAL COVERAGE ANALYSIS

- Complete and include the Noridian checklist for an IDE pre-approval packet submission.
- Email all required documents, (as attachments), to: iderequests@noridian.com

REFERENCES:
https://med.noridianmedicare.com/web/jea/policies/ides
https://med.noridianmedicare.com/web/jeb/policies/ide

Packet submission via email should provide the fastest turn-around time for approval. The attachments *, should be on UCSF letterhead. Upon receipt of the Noridian approval letter, subject accrual may begin. To ensure compliance with the UCSF record-retention policy, a copy of the Noridian approval letter, along with all submission documents are to be retained and uploaded to OnCore.

SOP CREATION AND APPROVAL HISTORY

Creation Date: 06/01/2014
Final Approval  

Reviewed by:  
Susanne Hildebrand-Zanki, AVC Research  
Jennifer Kellen, Clinical Trial Business Support Center (CTBSC)  
Greg Nalbandian, Investigational Trials Resource (ITR)  
Carol Maguire, Division of Cardiology

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