The National Medicare Clinical Trial Policy (formerly known as National Coverage Determination 310.1) necessitates a priori delineation of which clinical trial services/procedures can be billed to Medicare, and which could only be billed to the study. Such delineation can be expressed in Coverage Analysis.

The Research Billing Compliance Program at UC Davis was developed to ensure appropriate billing practices related to research protocols. The program performs Billing Reviews of selected protocols for accurate regulatory and billing practice activity. This review process ensures that research costs are billed appropriately in accordance with the Coverage Analysis for that study.

Per P&P 2317 Coverage Analysis is mandatory for all studies that have one of the following characteristics:

- Utilize a drug or device;
- Involve any charge or billing component (including billing to a third-party insurance, study sponsor, or patient);
- Include, as part of their protocol, any clinical intervention, including the invasion of any participant (control or subject’s) body cavity (e.g. blood draw) when such an intervention takes place within a UC Davis Medical Center licensed facility.

Coverage Analysis is a process of determining when a clinical study qualifies for Medicare coverage according to the rules in the National Policy NCD 310.1. Billing for all protocol related services must be listed in a Billing Grid. The grid identifies which study-related items and services can be paid by the third party payor, including Medicare, and which should only be paid by the study sponsor. At UC Davis Medicare coverage criteria is used to build all billing grids. Insurance policies vary in their coverage of clinical studies; therefore, it is important that the study participant confirm coverage with his/her individual insurance company.

Using Coverage Analysis for Trial Management

The flow chart below explains how Coverage Analysis and Billing Grid are used for trial management.

Steps in the process
The Coverage Analysis consists of two steps:

1. Qualification
2. Documenting all clinical trials procedures and services in a Billing Grid (excel spreadsheet)

Qualification Process

Qualification consists of a series of questions and can be completed in the Bridge. The Bridge is a separate database housed in Redcap.

Principal investigators must attest to Medicare that a clinical study meets certain Medicare qualifying criteria. When the study meets this criteria, 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. This attestation is achieved when answering specific questions during the Coverage Analysis process.

To start the Coverage Analysis process:

1. Get access to the Bridge see instructions in SOP#13
2. Once in the database, click on the "Clinical Trials Data Bridge" in "My Projects" list
3. Click on link under data collection section "IRB + EMR + OCT" Data
4. Find your study by IRB number in the "incomplete" or "complete" records dropdown menu
5. Answer specific questions to determine if the study qualifies.
6. Upload the "Billing Grid" spreadsheet
7. PI attests that all information is true and correct
8. Add Kuali (DaFis) numbers for finance staff to track study charges
9. Once all data is entered click "Ready For Upload", "Complete", "Save Record"
10. This data will be saved and uploaded to EMR to create a "Research Study Record" within 24 hrs
11. For more information on "Research Study Record" in EMR click here

Knowing whether a study is a qualified study is very important for both budget purposes and billing compliance. If the study qualifies, then in addition to Standard of Care, other procedures could be billed to insurance. All items and services in the study protocol must be listed in the Billing Grid spreadsheet. Items and services that may be covered include:

- Services to monitor effects of investigational drug/device
- Services to administer investigational drug/device (e.g., infusions, surgery)
- Services to prevent, diagnose, and treat complications

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.

Example of Qualification completed in the Bridge
Qualification of Device Clinical Trials

CMS (Centers for Medicare and Medicaid Services) determines Medicare coverage of device studies. Prior to enrolling any Medicare patients in an IDE study you must receive proof of approval from CMS and notify the local Medicare contractor (Noridian) that you are participating in an IDE study. When CMS approves the trial, the trial is listed on their web site as approved.

Noridian requires the following documentation:

a. Notice of participation in the trial
b. IDE designator assigned by the FDA (A or B)
c. Clinical trial number as listed on www.clinicaltrials.gov
d. PTAN of the facility - what is this?
e. Names of the principal investigator, study doctors and their national Provider Identification Number (NPI)

Such notice is necessary to input into the Noridian claims payment systems to assure proper processing of our provider's claims related to such trial. For further information on this process, visit the CMS website: [http://www.cms.gov/Medicare/Coverage/IDE/index.html](http://www.cms.gov/Medicare/Coverage/IDE/index.html)

See the device flowchart detailing the process for filing for Medicare approval of devices

Contact: Suzan Bruce, Research Coder, CTO

Billing Grid for Qualified Clinical Trials

If the study qualifies for Medicare coverage (and other insurance by extension), the study procedures and services specified in the protocol are listed in the Billing Grid (Excel spreadsheet). Each procedure is reviewed in detail to determine which would be reimbursed by Medicare and why. The preparation of the Billing Grid requires knowledge of CPT codes and Medicare coverage guidelines. Many hospital procedures, especially surgical and laboratory may contain multiple “bundled” codes. To estimate true cost of the procedure see [Epic Cost Query Tool](http://www.cms.gov/Medicare/Coverage/IDE/index.html) in the budgeting section.

A “Preliminary Billing Grid” can be prepared based on the Medicare and billing policies. A sponsor may decide to pay for a service/procedure regardless of Medicare rules. This should be reflected in a Clinical Trials Agreement and the negotiated budget. Once the budget is approved and the CTA is signed, the Billing Grid for this study should be updated to reflect the changes. At this point, it is called “Final Billing Grid.” The final Billing Grid is uploaded to the “Bridge.”
Steps to develop the Billing Grid:

1. Access the Billing Grid - Template
2. Add the title of study and primary objective of the study
3. Transfer all clinical events in to a spreadsheet. Use Schedule of Events from the protocol as a basis.
4. Contact a coder or biller to determine billing rules for procedures.
5. Review the protocol with a coder to understand what codes are billable to insurance or sponsor
6. Read protocol carefully and add other line items that may have been unclear or missed in the billing grid
7. Talk to the PI to see what procedures are standard of care at UC Davis Health
8. Update Billing Grid with billing determinations once CTA/Budget is final (S=Study pays, P=Patient/Insurance pays)
9. Upload Billing Grid to "Bridge" when final
10. Use Billing Grid as a billing map when performing Billing Review
11. See SOP#4 for detailed instructions regarding Coverage Analysis
12. Request assistance from Suzan Bruce for questions related to developing your Billing Grid: skbruce@ucdavis.edu

Below is an example of the Billing Grid (S=Study pays, P=Patient/Insurance pays):

<table>
<thead>
<tr>
<th>Items/Services</th>
<th>CPT Code</th>
<th>Initial visit</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic Visit Level 1</td>
<td>99201</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>this item is medically necessary</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>N/C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>this item is not separately billable</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>31622</td>
<td></td>
<td>P</td>
<td></td>
<td></td>
<td>this item is medically necessary</td>
</tr>
<tr>
<td>Blood Draw</td>
<td>85027</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td></td>
<td>provided by the sponsor</td>
</tr>
<tr>
<td>X Ray</td>
<td>71250</td>
<td></td>
<td></td>
<td></td>
<td>S</td>
<td>provided by the sponsor</td>
</tr>
<tr>
<td>WonderDrug</td>
<td>J999</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td>provided by the sponsor at no charge</td>
</tr>
</tbody>
</table>

Medicare Advantage Plans

If your study enrolls patients with a Medicare Advantage Plan, be aware of special requirements for copays and claims processing. For a Medicare patient in a qualifying clinical trial device study, the claims go to the Medicare Advantage Plan. For a Medicare patient in all other qualifying clinical trial studies (drug, etc.), the claims go to regular Medicare (Fee for Service). It is critical that research staff communicate with the registration staff when a Medicare Advantage enrollee is receiving a research service. The correct insurance plan code must be chosen during registration to route the claims and adjust the proper co-payment amounts. For updated information on the Medicare Advantage Plan billing, see: instructions

The Clinical Research Budgeting and Billing course (LMS# 09155). This training program provides an orientation to the financial and administrative infrastructure that supports clinical research billing across UC Davis Health. For more information see the ACRP eLearning Module "Managing Billing Compliance Risk: Navigating Medicare in Clinical Trials."

Key references:

- UCDMC P&P 2317 DOCUMENTATION OF RESEARCH STUDIES AND PARTICIPANTS IN THE BRIDGE AND ELECTRONIC MEDICAL RECORD SYSTEMS (PDF - Staff Only)
- CTSC SOP #4 Coverage Analysis (PDF - Staff Only)
- CTSC SOP#13 CREATE AND MANAGE RESEARCH STUDIES IN EMR/EPIC (PDF - Staff Only)
- UC Davis Clinical Research Guidebook
- The key Federal law and Modifier Information: National Medicare Clinical Trial Policy (also called National Medicare Coverage Determination NCD 310.1)
- California Coverage Laws: Noridian JE Part A and Part B Local Coverage Policies (Medical Policies)
- California Law SB37
- Medicare Coverage Database (database of Medicare Policies)
- Medicare Benefit Manual (includes information about services that are a benefit of Medicare).
- Managed Care Benefit Manual (includes information about Medicare Advantage Patients).
- IDE Approval Forms (Noridian IDE Policy: https://med.noridianmedicare.com/web/jea/policies)California Law SB37
Related articles

- Coverage Analysis
- Patient Zero Compliance Review
- Internal Budget in Unified Budget Template (UBT)
- Negotiate Sponsor budget
- Payments to Study Participants