

COVERAGE ANALYSIS

Coverage Analysis = QCT Form (Part 1) + Billing Grid (Part 2)

UCDAVIS
HEALTH SYSTEM

**Clinical and Translational
Science Center**

PART 1 – Qualifying Clinical Trials Form (QCT)

Instructions: Use this QCT form to determine when a trial is considered qualified to bill Medicare. If qualified, then the Billing Grid (part 2 of CA) is required. To access the Billing Grid template [click here](#). Questions regarding this form can be emailed to suzan.bruce@ucdmc.ucdavis.edu

Date Prepared:	Prepared By:	Department:
Principal Investigator Name and Signature:		Study Coordinator:
Study Title:		
Sponsor:		Phase

STEP 1. Preliminary Analysis

1. Does your **NEW** study include patient care services billed in UC Davis Health System? Yes No
(patient care services = patient procedures on site, scheduled in UC Davis Health System)

If you checked "NO": STOP! Do not fill out the rest of the form. If you checked "YES": proceed to the next question if applicable, if not go to #3

2. If submitting study **MODIFICATIONS** to IRB, does your modification include changes to patient care services? Yes No

If you checked "NO": STOP! Do not fill out the rest of the form. If you checked "YES": complete Billing Grid to reflect modifications of billing codes

3. Does the sponsor pay for ALL services? Yes No
("All services" = standard of care required by protocol, research procedures, study drug or device itself, expanded care. Nothing is billed to insurance)

If you checked "YES": STOP! Do not fill out the rest of the form. Complete Billing Grid to correctly capture all costs. You may use worksheet on page 2 to get started. If you checked "NO": proceed to the next question

STEP 2. Does this trial qualify to bill patient care services under Medicare Rules? To determine, follow the questionnaire below

SECTION 1: Requirements for Medicare Coverage of Routine Costs (check all that apply)

1. Is the trial's subject or purpose to evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage? Yes No
(Medicare Benefit Category listed on [NCD](#))
2. Does the trial have therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology? Yes No

Quote the objective that supports this:

3. Does the trial enroll patients with a diagnosed disease/condition rather than only healthy volunteers? Yes No

If you checked "NO" to any question listed in section 1, STOP – trial does not qualify for Medicare coverage; the Billing Grid is not required. If you checked "YES" to all questions in section 1, proceed to section 2.

SECTION 2: Automatically Qualifying "Deemed" Trials (check all that apply)

1. Funded by NIH, CDC, AHRQ, CMS, DOD and VA? Yes No
2. Funded by centers or cooperative groups supported by the above agencies? Yes No
3. Conducted under an Investigational New Drug application (IND) reviewed by the FDA? Yes No
4. Exempt from having an IND under 21 CFR 312.2.(b) (1)? Yes No

If you checked "YES" to any 1 of 4 questions in this section STOP – trial meets requirements for coverage under Medicare rules. The Billing Grid is required. If you checked "NO" to all 4 questions, proceed to next section.

SECTION 3: "Desirable" Characteristics (check all that apply)

1. Is the principal purpose of the trial to test whether the intervention potentially improves the participants' health outcome? Yes No
2. Is the trial well supported by available scientific and medical information or intended to clarify or establish the health outcomes of interventions already in common clinical use? Yes No
3. Do you agree that the trial does not unjustifiably duplicate existing studies? Yes No
4. Is the trial's design appropriate to answer the research question being asked? Yes No
5. Is the trial sponsored by a credible organization? Yes No
6. Is the trial in compliance with the Federal regulations relating to the protection of human subjects? Yes No
7. Are all aspects of the trial conducted according to the appropriate standards of scientific integrity? Yes No

If you checked "NO" to any question, STOP – trial is determined not to qualify for coverage under Medicare rules. The Billing Grid is not required. If you checked "YES" to all 7 questions trial meets requirements for Medicare coverage. The Billing Grid is required. See Conclusion section.

CONCLUSION: Does this trial qualify for Medicare coverage?

- Yes** – Proceed to Part 2 of Coverage Analysis, [Billing Grid](#)
- No** – STOP – Part 2, Billing Grid is not required

