

Medicare Coverage Analysis Worksheet

To be completed by the Principal Investigator of any clinical research studies involving investigational items or services, and a billing plan that includes an intent to bill study-required items/services to study participants and/or their insurance. *Note: Do not use for IDE device studies; IDE studies must follow CMS IDE pre-approval rules.*

Study Title:

Does this Study meet the qualifying criteria* for Medicare Coverage?

**Per the Medicare National Coverage Determination (NCD) for Routine Costs in Clinical Trials and Research Studies (310.1)*

STEP 1: Do ALL 3 Columns Below Apply? (mark all that apply)

Medicare Benefit Category
(Not excluded from Medicare
as a Benefit Category)

Therapeutic Intent must be
included in study aims
(Not designed exclusively to
test toxicity or pathophysiology)

Must enroll patients with
**Diagnosed Disease or
Condition** (can include
controls)

YES

NO

STEP 2: Do ANY of the 5 Columns Below Apply? (mark all that apply)

Study is
funded by the
Government
(NIH, CDC,
AHRQ, CMS,
DOD, VA)

Study is
**supported
by groups
funded by
the
Government**
(NIH, CDC,
AHRQ, CMS,
DOD, VA)

Study
conducted
under IND
reviewed
by the FDA

Study is
**Exempt
from IND**
under 21
CFR
312.2(b)(1)

All of the following are true:

- 1) The principal purpose of the study is to test whether the intervention potentially improves the participants' health outcomes;
- 2) The study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
- 3) The study does not unjustifiably duplicate existing studies;
- 4) The study design is appropriate to answer the research question being asked in the trial;
- 5) The study is sponsored by a credible organization or individual capable of executing the proposed study successfully;
- 6) The study is in compliance with Federal regulations relating to the protection of human subjects; and
- 7) All aspects of the study are conducted according to the appropriate standards of scientific integrity.

YES

NO

Study is Medicare Qualifying

Principal Investigator must provide Z00.6 diagnosis code and Q0/Q1 modifiers on all services or items that will be billed to Medicare.

Study Does Not Qualify

Study-required services or items may NOT be billed out to Medicare or any 3rd party payers that follow Medicare rules.

Principal Investigator Signature: _____

Date: _____

By signing this form, you are acknowledging that ALL information submitted for this study, including this worksheet, accurately reflects the requirements of the study protocol & billing plan.