Attachment 1

MEDICARE QUALIFYING CLINICAL TRIALS FLOWCHART
(Source: Medicare National Coverage Decision-NCD)

- Does the trial evaluate an item or service that falls within a Medicare benefit category (e.g., physician’s service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids)?
- Does the trial have therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology?
- If the trial evaluates a therapeutic intervention, does it enroll patients with diagnosed disease rather than healthy volunteers? (Trials of diagnostic intervention may enroll healthy patients as a control group.)

**NO**

**YES**

Is the trial:
- Funded by NIH, CDC, AHRQ, CMS, DOD, VA; **OR**
- Supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or VA; **OR**
- Conducted under an IND reviewed by the FDA; **OR**
- Exempt from having an IND under 21 CFR 312.2(b)(1) (until qualifying criteria are developed and certification process is in place?) (See below for exemptions from IND under the regulations)

Project **DOES NOT** qualify for Medicare coverage under NCD

**NO**

**YES**

May bill Medicare for routine costs of trial when the involved items and services are otherwise available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision.)

Routine costs include items or services:
- Typically provided outside of a clinical trial (e.g., medically necessary conventional care)
- Required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapy agent); clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- 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.

May **not** bill Medicare for:
- The investigational device, drug, or procedure itself (except for Category B devices identified as such and not previously deemed non-covered).
- Items and services provided solely to determine trial eligibility.
- Items and services provided solely to satisfy data collection and analysis needs and not used in direct clinical patient management (e.g., monthly CT scans for a condition usually requiring a single CT scan).
- Items and services customarily provided by sponsor without charge.
- Items and services for which sponsor has specifically paid provider.
- Items and services for which there is no Medicare benefit category.
- Non-covered items and services because they are statutorily excluded or fall under a national non-coverage policy.

**Exemptions allowed under 21 CFR 312(b)(1):** The purpose of the research is not intended to change the drug indications or labeling, advertising, route of drug administration or dosage, or patient population and the trial will undergo IRB review and approval as well as meet all other federal regulations.

**Note:** A process for self-certifying under the NCD has not yet been established by CMS.

August, 2017