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Dear Ms. Baer:

Thank you for your letter regarding the Clinical Trial Policy (CTP) National Coverage Determination (NCD). As you know, in 2000, President Clinton directed the Medicare program to revise its payment policy to explicitly reimburse providers for the cost of routine patient care associated with participation in clinical trials, and to take additional action to promote the participation of Medicare beneficiaries in clinical trials, providing access to cutting-edge treatment for Americans with diseases such as cancer, heart disease, Alzheimer’s, Parkinson’s, and diabetes. We broadly interpreted the Executive Memorandum to allow the most expansive access to clinical trials by Medicare beneficiaries, while ensuring that they participate in trials that are of the highest quality.

1. With that in mind, a clinical trial receiving Medicare coverage of routine costs under the CTP NCD must meet the following three requirements: The subject of purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category.
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage under the CTP. Therefore, the following seven desirable characteristics must also be met for clinical trials to be CMS-approved.

- The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.
- The trial 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.
- The trial does not unjustifiably duplicate existing studies.
- The trial design is appropriate to answer the research question being asked in the trial.
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully.
- The trial is in compliance with Federal regulations relating to the protection of human subjects; and
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Clinical trials are deemed to be automatically qualified (i.e., meet the seven desirable characteristics) if the:

- Trials are funded by NIH, CDC, AHRQ, CMS, DOD, and VA.
- Trials are supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA.
- Trials are conducted under an investigational new drug application (IND) reviewed by the FDA; and drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs.

With regard to your specific question of how CMS defines “trials supported by centers or cooperative groups,” we believe if a trial is conducted at a cooperative center or research center that is funded by NIH, CDC, AHRQ, CMS, DOD, or VA, we assume that the center supports trials that have these qualities. Examples of “centers” are the NCI Clinical Trials Cooperative Groups, the NIDDK Urology Cooperative Research Centers Program, the NIAID Cooperative Centers for Translational Research on Human Immunology and Biodefense, or the VA Cooperative Studies Program.

We applaud your work in facilitating Medicare beneficiaries’ access to clinical research.

Sincerely,

Patrick Conway, MD, MSc
Deputy Administrator for Innovation and Quality
and CMS Chief Medical Officer