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Medical Policy

Clinical Trials – WEA Secondary Insurance

Policy Number: 1032

Policy History			
Approve Date:	01/13/2015	Effective Date:	01/13/2015
Reviewed/Revised Date:	01/13/2016, 01/13/2017, 01/13/2018, 04/29/2019, 04/28/2020		

Preauthorization	
All Plans	Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details.

Policy

Indications of Coverage

This policy also applies to members with Medicare Primary insurance and secondary commercial insurance. WEA Med-Plus policy holders are subject to the criteria as per NCD 310.1 National Coverage Determination for Routine Costs in Clinical Trials.

Indications and Limitations of Coverage

I. Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

   Routine costs of a clinical trial include all items and services that are otherwise generally 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) that are provided in either the experimental or the control arms of a clinical trial except:
   A. The investigational item or service, itself unless otherwise covered outside of the clinical trial
   B. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan) AND
   C. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial

II. Routine costs in clinical trials include:
   A. Items or services that are typically provided absent a clinical trial (e.g., conventional care)
   B. Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications AND
   C. Items or services 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

This policy does not withdraw Medicare coverage for items and services that may be covered according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare Administrative Contractor local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited; Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100-03, National Coverage Determination (NCD) Manual, and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

Requirements for Medicare Coverage or Routine Costs

I. Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements
   A. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids)
   B. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent
   C. 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

II. The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:
   A. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes
   B. 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
   C. The trial does not unjustifiably duplicate existing studies
   D. The trial design is appropriate to answer the research question being asked in the trial
   E. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully
   F. The trial is in compliance with Federal regulations relating to the protection of human subjects and
   G. All aspects of the trial are conducted according to the appropriate standards of scientific integrity

Qualification Process for Clinical Trials

I. Using the authority found in §1142 of the Social Security Act (the Act) (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to the Centers for Medicare & Medicaid Services (CMS).

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.

Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.

II. Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

A. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA
B. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA
C. Trials conducted under an investigational new drug application (IND) reviewed by the FDA
D. 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. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.

   The CMS, through the NCD process, through an individualized assessment of benefits, risks, and research potential, may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD.

   Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS's Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.

Also see:
Clinical Trials – WEA Primary Insurance

Background

Clinical trials are prospective biomedical or behavioral research studies on human subjects that are designed to answer specific questions about biomedical or behavioral interventions (novel vaccines, drugs, treatments, functional foods, dietary supplements, devices or new ways of using known interventions), generating safety and efficacy data.[1] They are conducted only after satisfactory information has been gathered that satisfies health authority/ethics committee approval in the country where approval of the therapy is sought.

References

The above policy is based on the following references:

1. Wisconsin Statute: 632.87
2. Centers for Medicare & Medicaid Services (CMS): National Coverage Determination for Routine Costs in Clinical Trials (310.1)