NCD for Routine Costs in Clinical Trials (310.1)

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100-3

Manual Section Number

310.1

Version Number

2

Effective Date of this Version

7/9/2007

Implementation Date

10/9/2007

Benefit Category

Ambulance Services
Ambulatory Surgical Center Facility Services
Antigens
Artificial Legs, Arms, and Eyes
Audiology Services
Blood Clotting Factors for Hemophilia Patients
Bone Mass Measurement
Certified Nurse-Midwife Services
Certified Registered Nurse Anesthetist Services
Chiropractor Services
Clinical Nurse Specialist Services
Clinical Social Worker Services
Colorectal Cancer Screening Tests
Comprehensive Outpatient Rehabilitation Facility (CORF) Services
Critical Access Hospital Services
Dentist Services
Diabetes Outpatient Self-Management Training
Diagnostic Laboratory Tests
Diagnostic Services in Outpatient Hospital
Diagnostic Tests (other)
Diagnostic X-Ray Tests

Drugs and Biologicals
Durable Medical Equipment
Erythropoietin for Dialysis Patients
Extended Care Services
Eyeglasses After Cataract Surgery
Federally Qualified Health Center Services
Hepatitis B Vaccine and Administration
Home Dialysis Supplies and Equipment
Home Health Services
Hospice Care
Immunosuppressive Drugs
Incident to a physician's professional Service
Influenza Vaccine and Administration
Inpatient Hospital Services
Inpatient Psychiatric Hospital Services
Institutional Dialysis Services and Supplies
Leg, Arm, Back, and Neck Braces (orthotics)
Medical Nutrition Therapy Services
Nurse Practitioner Services
Optometrist Services
Oral Anticancer Drugs
Oral Antiemetic Drugs
Orthotics and Prosthetics
Osteoporosis Drug
Outpatient Hospital Services Incident to a Physician's Service
Outpatient Occupational Therapy Services
Outpatient Physical Therapy Services
Outpatient Speech Language Pathology Services
Partial Hospitalization Services
Physician Assistant Services
Physicians' Services
Pneumococcal Vaccine and Administration
Podiatrist Services
Post-Hospital Extended Care Services
Post-Institutional Home Health Services
Prostate Cancer Screening Tests
Prosthetic Devices
Qualified Psychologist Services
Religious NonMedical Health Care Institution
Rural Health Clinic Services
Screening for Glaucoma
Screening Mammography
Screening Pap Smear

Screening Pelvic Exam
Self-Care Home Dialysis Support Services
Shoes for Patients with Diabetes
Skilled Nursing Facility
Splints, Casts, Other Devices Used for Reduction of Fractures and Dislocations
Surgical Dressings
Transplantation Services for ESRD-Entitled Beneficiaries
X-ray, Radium, and Radioactive Isotope Therapy

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Indications and Limitations of Coverage

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:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- 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
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the

prevention of complications; and
- 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 medical review policies (LMRPs) or the regulations on category B investigational device exemptions (IDE) 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 contractors' local policies.

For noncovered 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 noncovered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national noncoverage policy in Pub. 100-03, 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 noncovered item or service, itself, will not.

A. Requirements for Medicare Coverage of Routine Costs

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

- 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).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- 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 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:

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

B. Qualification Process for Clinical Trials

Using the authority found in §1142 of 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 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.

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

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. 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 national coverage determination (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.

Should CMS find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j)(4) of the Act, as applicable. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial's principal investigator may be pursued.

Medicare regulations require Medicare+Choice (M+C) organizations to follow CMS's national coverage decisions. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members' care, but cannot require prior authorization or approval.

(This NCD last reviewed July 2007.)

Transmittal Number

74

Transmittal Link

http://www.cms.hhs.gov/transmittals/downloads/R74NCD.pdf

Revision History

09/2000 - Implemented new policy covering routine costs in clinical trials. Effective and implementation dates 09/19/2000. (TN 126) (CR 1241)

09/2007 - Effective Date: 07/09/2007. Implementation Date: 10/09/2007. (TN 74) (CR5719)

Claims Processing Instructions

- TN 1418 (Medicare Claims Processing)
- TN 310 (One Time Notification)
- MM5805 (MLN Matters Articles 5805)
- MM5790 (MLN Matters Articles 5790)

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with NCAs, from the National Coverage Analyses database.

- First reconsideration for Clinical Trial Policy (CAG-00071R)
- Second reconsideration for Clinical Trial Policy (CAG-00071R2)

Other Versions

Routine Costs in Clinical Trials - Version 1, Effective between 09/19/2000 - 07/09/2007

National Coverage Determination for Routine Costs in Clinical Trials, (310.1). (2007, July 9).

Retrieved February 10, 2010, from Centers for Medicare & Medicaid Services, website:

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials