
Medicare Coverage Issues Manual

Department of Health and Human
Services (DHHS)
HEALTH CARE FINANCING
ADMINISTRATION (HCFA)

Transmittal 126

Date: SEPTEMBER 19, 2000

CHANGE REQUEST 1241

<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
Table of Contents	2 pp.	2 pp.
30-1	4 pp.	-----

NEW/REVISED MATERIAL--*EFFECTIVE DATE: September 19, 2000*
IMPLEMENTATION DATE: September 19, 2000

Section 30-1, Routine Costs of Clinical Trials, creates a new section to implement new policy to cover routine costs in clinical trials. This policy is in accordance with the June 7, 2000, executive memorandum from the President of the United States to provide coverage of routine patient care costs in clinical trials.

This national coverage policy is based upon the authority found in §1862(a)(1)(E) of the Social Security Act (the Act). It is binding on all Medicare carriers, intermediaries, peer review organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, and Medicare+Choice organizations (§1852(a)(1)(A) of the Act). In addition, an administrative law judge may not disregard, set aside, or otherwise review a national coverage decision issued under §1862(a)(1) of the Act. 42 C.F.R. §405.860

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previous published in the manual and is only being reprinted.

Funding is available through the Supplemental Budget Request process for costs required to implement these instructions.

COVERAGE ISSUES

Clinical Trials

| Routine Costs in Clinical Trials

30-1

Medical Procedures

Colonic Irrigation	35-1
Manipulation	35-2
Heat Treatment, Including the Use of Diathermy and Ultrasound for Pulmonary Conditions	35-3
Ultrasonic Surgery	35-4
Cellular Therapy	35-5
Thermogenic Therapy	35-6
Carotid Body Resection/Carotid Body Denervation	35-7
Acupuncture	35-8
Phaco-Emulsification Procedure-Cataract Extraction	35-9
Hyperbaric Oxygen Therapy	35-10
Sterilization	35-11
Plastic Surgery to Correct "Moon Face"	35-12
Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections With Sclerosing Agents	35-13
Consultations With a Beneficiary's Family and Associates	35-14
Postural Drainage Procedures and Pulmonary Exercises	35-15
Vitrectomy	35-16
Induced Lesions of Nerve Tracts	35-17
Electrosleep Therapy	35-18
Intravenous Histamine Therapy	35-19
Treatment of Motor Function Disorders With Electric Nerve Stimulation	35-20
Inpatient Hospital Pain Rehabilitation Programs	35-21
Outpatient Hospital Pain Rehabilitation Programs	35-21.1
Inpatient Hospital Stays for the Treatment of Alcoholism	35-22
Outpatient Hospital Services for Treatment of Alcoholism	35-22.1
Treatment of Drug Abuse (Chemical Dependency)	35-22.2
Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic	35-22.3
Chemical Aversion Therapy for Treatment of Alcoholism	35-23
Electrical Aversion Therapy for Treatment of Alcoholism (Electroversion Therapy, Electro-Shock Therapy, Noxious Paradic Stimulation)	35-23.1
Diagnosis and Treatment of Impotence	35-24
Cardiac Rehabilitation Programs	35-25
Treatment of Obesity	35-26
Supplemented Fasting	35-26.1
Biofeedback Therapy	35-27
Oxygen Treatment of Inner Ear/Carbon Therapy	35-29
Blood Platelet Transfusions and Bone Marrow Transplantation	35-30
Stem Cell Transplantation	35-30.1
Treatment of Decubitus Ulcers	35-31

COVERAGE ISSUES

Medical Procedures

Vertebral Artery Surgery	35-32
Intestinal By-Pass Surgery	35-33
Fabric Wrapping of Abdominal Aneurysms	35-34
Therapeutic Embolization	35-35
Extracranial-Intracranial (EC-IC) Arterial Bypass Surgery	35-37
Ultrafiltration, Hemoperfusion and Hemofiltration	35-38
Intraocular Photography	35-39
Gastric Bypass Surgery for Obesity	35-40
Diathermy Treatment	35-41
Withdrawal Treatments for Narcotic Addictions	35-42
Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery	35-44
Cardiac Catheterization Performed in Other Than a Hospital Setting	35-45
Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy	35-46
Breast Reconstruction Following Mastectomy	35-47
Osteogenic Stimulation	35-48
Hyperthermia for Treatment of Cancer	35-49
Cochleostomy with Neurovascular Transplant for Meniere's Disease	35-50
Hemodialysis for Treatment of Schizophrenia	35-51
Laser Procedures	35-52
Adult Liver Transplantation	35-53
Pediatric Liver Transplantation	35-53.1
Refractive Keratoplasty	35-54
Transvenous (Catheter) Pulmonary Embolectomy	35-55
Fluidized Therapy Dry Heat for Certain Musculoskeletal Disorders	35-56
Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature	35-57
Electroencephalographic (EEG) Monitoring During Open-Heart Surgery	35-57.1
Thoracic Duct Drainage (TDD) in Renal Transplants	35-58
Endoscopy	35-59
Apheresis (Therapeutic Pheresis)	35-60
Transsexual Surgery	35-61
Invasive Intracranial Pressure Monitoring	35-62
Tinnitus Masking	35-63
Chelation Therapy for Treatment of Atherosclerosis	35-64
Gastric Freezing	35-65
Treatment of Psoriasis	35-66
Melodic Intonation Therapy	35-67
Implantation of Anti-Gastroesophageal Reflux Device	35-69
Closed-Loop Blood Glucose Control Device (CBGCD)	35-70

30-1 ROUTINE COSTS IN CLINICAL TRIALS

Effective for items and services furnished on or after September 19, 2000, 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 noncoverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

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

Routine costs in clinical trials include:

- o Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- o 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
- o 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 or the regulations on category B investigational device exemptions (IDE) found in 42 C.F.R. §405.201-405.215 and §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. (Refer to MCM §§2300.1 and MIM 3101.) However, if the item or service is not covered by virtue of a national noncoverage policy in the Coverage Issues 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:

1. 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).
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 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 HCFA.

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, HCFA, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, 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.

Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified or have certified that they meet the qualifying criteria unless HCFA'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 HCFA 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 HCFA'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.