

# http://www.cms.hhs.gov/ClinicalTrialPolicies/

Overview - Microsoft Internet Explorer

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Medicare Clinical Trial Policies

» Overview

## Overview

Clinical trials are research studies designed to evaluate the safety and effectiveness of medical care. They are key to understanding the appropriate use of medical interventions of all types and informing payers about what services to cover. Previously, Medicare has not paid for items and services related to clinical trials because of their experimental nature. As a result, only a very small percentage of American seniors participate in clinical trials, although the elderly bear a disproportionate burden of disease in the United States.

2000年9月から本格導入

ted States issued an executive memorandum directing the Secretary y authorize [Medicare] payment for routine patient care costs...and ated with participation in clinical trials." In keeping with the efining the routine costs of clinical trials and identifying the clinical trials for which payment for such routine costs should be made.

### Downloads

- [Proposed National Coverage Decision \(PDF, 48KB\)](#)
- [Final National Coverage Decision \(PDF, 31KB\)](#)
- [Program Memorandum \(PDF, 105KB\)](#)
- [Provider Bulletin \(PDF, 57KB\)](#)
- [Federal Register Notice Announcing 10/20/00 Meeting \(PDF, 127KB\)](#)
- [Federal Register Notice Announcing 11/20/00 Meeting \(PDF, 128KB\)](#)

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## 公的助成を受けている 臨床試験における通常診療経費は保険診療とする

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# どのような臨床試験が対象となるのか

## ▪ **Deemed Trials.**

Some trials are considered automatically deemed as having desirable characteristics. They include:

*Effective September 19, 2000*

- **Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DOD), and Department of Veterans Affairs (VA);**
- **Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;**
- **Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drugs Administration (FDA);**

etc

# 米国 臨床試験にかかるRoutine Cost とは

**Routine costs DO include (and are therefore covered):**

- **Items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care);**
- **Items and services required for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent),**
- **Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and**
- **Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.**

# Coverage with Evidence Development (CED)

The screenshot shows the CMS website interface. At the top left is the U.S. Department of Health & Human Services logo. The main header features the CMS logo and the text "Centers for Medicare & Medicaid Services". A search bar is located on the right. Below the header is a navigation menu with links for Home, Medicare, Medicaid, SCHIP, About CMS, Regulations & Guidance, Research, Statistics, Data & Systems, Outreach & Education, and Tools. A secondary menu includes links for People with Medicare & Medicaid, Questions, Careers, Newsroom, Contact CMS, Acronyms, Help, Email, and Print. The breadcrumb trail reads: CMS Home > Site Tools & Resources > Media Release Database > Press Releases. The main content area is titled "Media Release Database" and "Press Releases". A sidebar on the left lists: Overview, Press Releases, Fact Sheets, Testimonies, and Speeches. The main content displays a press release titled "Details for: MEDICARE REVISES GUIDANCE FOR NATIONAL COVERAGE DETERMINATIONS WITH EVIDENCE DEVELOPMENT". Below the title is a "Return to List" button. The release date is "Wednesday, July 12, 2006" and the contact information is "CMS Office of Public Affairs, 202-690-6145". A large yellow text overlay on the right side of the page reads "2006年7月から本格導入". At the bottom of the page, another large yellow text overlay reads "登録事業や臨床試験への参加を条件に 有望な新規医薬品・医療技術へに保険償還を行う".

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**For Immediate Release:** Wednesday, July 12, 2006

**Contact:** CMS Office of Public Affairs  
202-690-6145

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