

Coverage of Cancer Clinical Trials

What is a clinical trial?

A clinical trial is a research study in which people volunteer to test new treatments, drugs, or procedures. Researchers use clinical trials to learn whether a new treatment works and is safe for people. This research is needed to develop new treatments, and clinical trials often provide patients with access to the highest quality of cancer care and new treatments before they are widely available.

How are clinical trials conducted?

Clinical trials are usually conducted in a series of four phases, or research testing steps.

- **Phase I:** This is the first step in testing a new drug or procedure with people. Researchers test safe dosages and methods of delivery (ex: given orally or injected into a vein or muscle). The researchers carefully observe any side effects.
- **Phase II:** These trials study both the safety and effectiveness of a treatment and evaluate how it affects your body. These studies are usually specific to one type of cancer, and often have less than one hundred patients.
- **Phase III:** These trials compare the new treatment with the current standard treatment. Participants are randomly assigned to the new treatment group or to the standard treatment group. Random assignment helps to avoid bias and ensures that other factors do not affect study results.
- **Phase IV:** These trials are useful in researching the long-term safety and overall effectiveness of treatment. These studies take place after a treatment has been approved for widespread use.

Who sponsors cancer clinical trials?

These are a few examples of agencies and companies that sponsor cancer clinical trials:

- National Cancer Institute
- National Institutes of Health
- Pharmaceutical & Biotechnology Companies
- U.S. Department of Defense
- U.S. Department of Veterans Affairs
- U.S. Food & Drug Administration

What are the costs of participating in a clinical trial?

Routine care costs are for care that is not dependent on a clinical trial and occurs when receiving standard treatment or participating in the study. Routine care costs can include lab tests, x-rays, blood work, and doctor visits.

Costs that are typically not covered by health insurance include the drugs or procedures being tested in the clinical trial, items or services used solely for the data collection needs of the trial, and anything being provided for free by the clinical trial sponsor.

Some health insurance plans will also not provide coverage for routine care costs because they consider clinical trials to be “experimental” treatment.

Does my state require insurance coverage for clinical trials?

There are currently **35 states** that require health insurance plans to cover the routine care costs of a clinical trial, including: Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, Wyoming, and the District of Columbia. However, each state's law is different. For more information on your state's regulation of health insurance coverage for clinical trials, please contact the CLRC or your state's insurance agency.

Example: In **California**, health insurance plans are required to cover the routine care costs associated with cancer clinical trials (CA Health & Safety Code §1370.6). Covered costs may include, but are not limited to, hospitalization, physician visits, X-rays, blood tests, CAT scans, and PET scans. In addition, some costs may be covered by the clinical trial sponsor, such as a pharmaceutical company.

Do Medicare and Medicaid cover clinical trials?

Medicare Part B does cover the routine care costs of clinical trials. For more information: www.cancer.gov/cancertopics/factsheet/support/medicare. Some states cover clinical trials under **Medicaid**. Contact your state Medicaid program for more information.

What if your insurance denies coverage for the clinical trial?

1. Contact your health care provider team to see if they can assist you
2. Contact your insurance company to find out why they denied coverage
3. Go through your insurance internal appeals process
4. Contact your state insurance agency to see if you are eligible for an external appeals process or independent medical review
Ex: California Department of Managed Health Care or California Department of Insurance
5. Contact the CLRC for assistance

Patient Protection and Affordable Care Act (Public Law 111-148):

Also known as healthcare reform, this law was passed on March 23, 2010, and states that beginning in 2014, insurance companies will be required to cover the costs associated with routine care for individuals who are enrolled in a clinical trial to treat cancer or other life-threatening diseases.

Current Federal Bills in Congress:

These bills are currently pending in Congress and if passed would increase access to clinical trials:

- **The 21st Century Cancer ALERT Act (S. 717, H.R.6224)**

For more information on these bills, please visit <http://thomas.loc.gov> or contact the CLRC.

For more information about or to locate cancer clinical trials:

Living Beyond Breast Cancer
<http://www.lbbc.org/Understanding-Breast-Cancer/Clinical-Trials-Research-Studies>

National Institutes of Health (NIH)
www.clinicaltrials.gov

ACS Clinical Trials Matching Database
www.cancer.org (800) 303-5691

SearchClinicalTrials.org
www.searchclinicaltrials.org
(877) MED-HERO

National Cancer Institute (NCI)
www.cancer.gov/clinicaltrials (800) 422-6237

TrialCheck
www.cancertrialshelp.org (877) 227-8451

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