

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). Safety is the main concern at this point, so doctors and researchers carefully observe for any side effects.

The main reason for doing phase I studies is to find the highest dose of the new treatment that can be safely administered without serious side effects. The first few people in the study often get a low dose of the treatment and are watched closely. If there are only minor side effects, the next few participants may get a higher dose. This process continues until doctors find the dose that's most likely to work while having an acceptable level of side effects.

- Phase II: If a new treatment is found to be reasonably safe in phase I clinical trials, it can then be tested in a phase II clinical trial to determine if it works. Phase II 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, often have less than one hundred patients, and all of the volunteers usually get the same dose.
- 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. Usually, neither the doctor nor the patient knows which of the treatments the patient is getting. This kind of random assignment helps to avoid bias and ensures that other factors do not affect study results. Most phase III clinical trials have a large number of patients, at least several hundred.

Submission for FDA Approval: In the U.S., when phase III clinical trials show a new drug is more effective and/or safer than the current standard treatment, a new drug

application (NDA) is submitted to the Food and Drug Administration (FDA) for approval. The FDA then reviews the clinical trial results and other relevant information. The FDA may then ask for more information or even require that more studies be done, extending the approval process. Or, based on its review, the FDA can decide that the treatment is ok to be used in patients, in which case, the new treatment often becomes the standard of care. However, in some cases the clinical trials are still not over and phase IV trials continue.

- 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 by the FDA 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.

However, as of 2014, under the Affordable Care Act (ACA), newer health insurance plans must cover the routine costs of care for people participating in clinical trials that meet certain requirements, and cannot discriminate against plan members for participating in clinical trials. An approved clinical trial must be federally funded, and must have an investigational new drug application (NDA) approved by the FDA or be excused from investigational new drug application requirements. Your doctor can help determine if the Affordable Care Act covers the clinical trial you’re considering. That being said, the clinical trials coverage provision of the Affordable Care Act does not apply to a “grandfathered” health plan, which is a plan that existed on or before the ACA went into effect. If you do not know if your plan is considered a grandfathered plan, contact your health insurance provider.

Does my state require insurance coverage for clinical trials?

Currently, **38 states and the District of Columbia** have laws or cooperative agreements requiring insurers to cover the routine patient costs associated with clinical trials. These laws are important for those who have grandfathered insurance policies not covered by the ACA. These states include: Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida (agreement), Georgia (agreement), Illinois, Indiana, Iowa, Kansas,

Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan (agreement), Missouri, Montana, Nebraska (agreement), Nevada, New Hampshire, New Jersey (agreement), New Mexico, North Carolina, Ohio, Oregon, Rhode Island, South Carolina (agreement), Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. The components of the laws vary significantly by state.

Example: In **California**, health insurance plans are required to cover the routine care costs associated with cancer clinical trials as long as the patient's treating physician recommends participation in the clinical trial after determining that such participation would potentially benefit the patient (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 covers the routine patient costs for qualifying clinical trials. For more information: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1>

Some states cover clinical trials under **Medicaid**. Contact your state Medicaid program for more information.

What if my 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. Submit an appeal to your insurance company, requesting that they reconsider the denial and provide coverage for the requested treatment. Your appeal should be based on the medical necessity of the clinical trial and why your physician feels that the clinical trial is the best treatment option for you. If there is enough information to show that the approach is safe and effective, your health plan may consider the approach "established" and cover some or all of the costs.
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. You can speak with the sponsor of the trial or one of the trial representatives to see if there are funds available through the trial sponsor to assist you.
6. Contact the CLRC for assistance.

For more information about or to locate cancer clinical trials:

- Living Beyond Breast Cancer: <http://www.lbbc.org/learn/treatments-and-research/clinical-trials>
- ACS Clinical Trials Matching Database: www.cancer.org (800) 303-5691
- National Cancer Institute (NCI): www.cancer.gov/clinicaltrials (800) 422-6237

- National Institutes of Health (NIH): www.clinicaltrials.gov
- SearchClinicalTrials.org: www.searchclinicaltrials.org (877) MED-HERO
- TrialCheck: www.cancertrialshelp.org (877) 227-8451

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