

Who Pays for Clinical Trials?

You may be wondering if clinical trials cost money and who pays for them.

Many clinical trial costs are covered by the sponsor of the study, a patient's insurance plan if one is available, and sometimes there are out-of-pocket costs. Before you join a study, ask the study coordinator which costs are covered and which are not.



Patient care costs in clinical trials

Paying for Clinical Trials



Learn about the different types of costs related to taking part in a clinical trial, and who is expected to pay for which costs.

Patient care costs are those costs that you would pay even if you weren't in a trial. These costs are often covered by health insurance.

Types of patient care costs may include:

- doctor visits
- hospital stays
- standard cancer treatments
- treatments to improve symptoms of cancer or side effects from treatment
- lab tests
- x-rays and other imaging tests

If you need to travel to take part in a study, other costs might include travel, lodging, meals, parking, or child and elder care. Sometimes trials can help cover these extra costs, so ask the research team if the study offers financial help or know of support organizations that offer help.

Research costs in clinical trials

Research costs are those costs that are related to taking part in the trial. Often these costs are not covered by health insurance. But they may be covered by the trial's sponsor.

Examples of research costs include:

- the study drug
- lab tests performed purely for research purposes
- added x-rays and imaging tests performed solely for the trial
- extra doctor visits that you would not have with usual care

When you take part in a trial, you may have extra doctor visits that you would not have with usual care. During these visits, your doctor carefully watches for side effects and your safety in the study.

Are clinical trials covered by insurance?

Before you join a trial, learn as much as you can about which costs you or your health plan need to pay and those that will be covered by the study. Talk with your doctor, the research team, and your health plan.

Ask your doctor if there is someone on staff who can help work with your health plan. This person might be a financial counselor or research coordinator. Or they might work in the hospital's patient finance department.

Ask the research coordinator or nurse if other people have had problems getting their health plans to cover routine patient care costs. If so, you might ask the research coordinator or nurse for help in sending information to your health plan that explains why this clinical trial might be a good fit for you. Items insurance companies may ask for include:

- medical journal articles that show possible patient benefits from the drug or procedure that is being tested
- a letter from your doctor that explains the trial or why it is a reasonable option for you
- support letters from patient advocacy groups

How to work with health insurance plans

Call your health insurance plan. If your doctor does not have a staff person to help work with health plans, call the customer service number on the back of your insurance card. Here are important questions to ask:

- Does the health plan cover routine patient care costs for people taking part in clinical trials?
- If so, is a pre-authorization required? A pre-authorization means the health plan will review information about the clinical trial before deciding to cover the patient care costs.
- If your health plan requires a pre-authorization, what information do you need to provide? Examples might include copies of your medical records, a letter from your doctor, and a copy of the informed consent form for the trial. If a pre-authorization is not required, you don't have to do anything else. But it is a good idea to request a letter from your health plan that states that a pre-authorization is not needed for you to take part in the clinical trial.
- Understand all the costs related to the trial. Ask your doctor or the trial's contact person about the costs that must be covered by you or your health plan.
- Work closely with your employer's benefits manager. This person may be able to help you work with your health plan.

• Give your health plan a deadline. Ask your doctor or the trial's contact person for a target date when you should start treatment. This can help to ensure that coverage decisions are made promptly.

What happens if my claim is denied?

If your claim is denied, contact your insurance plan's billing office for help. The billing manager may know how to appeal your health plan's decision.

You can also read your health insurance policy to find out what steps you can follow to make an appeal. Ask your doctor to help you. It might help if they contact the medical director of your health plan.

Joining a clinical trial without insurance

If you don't have insurance or have other financial worries that you think may prevent you from taking part in a clinical trial, there are places to go for help. See Managing Cancer Costs and Medical Information for advice and a list of resources.

Some screening, prevention, and quality-of-life studies take place at sites that serve people with low incomes through the NCI Community Oncology Research Program (NCORP). If you receive health care at one of these sites, you may be able to take part in a clinical trial.

People with cancer may be able to enroll in National Clinical Trials Network (NCTN) clinical trials through NCORP, as well. Check with the clinic where you receive care about studies that you might be eligible for.

Federal health insurance and programs for clinical trials

Some federal health insurance programs help pay the costs of care in clinical trials.

Medicaid is a US federal health insurance program for people who cannot afford regular medical care. Medicaid covers all routine patient care costs in a clinical trial. Each state has its own rules about who is eligible for Medicaid. Visit Medicaid.gov to learn more about your state's Medicaid program.

Medicare is a US federal health insurance program for people aged 65 years or older and people with certain disabilities. If you have Medicare, you may be reimbursed for some of the costs related to taking part in trials of new ways to diagnose or treat cancer. For more information, call Medicare at 1-800-MEDICARE (1-800-633-4227).

TRICARE is the Department of Defense's health care program. If you are covered under TRICARE, you can be reimbursed for the medical costs related to taking part in NCI-sponsored trials for cancer prevention and treatment. Find more information on the TRICARE's website.

The **Department of Veterans Affairs** allows eligible veterans to take part in NCI-sponsored clinical trials at Veterans Affairs Medical Centers. All phases and types of NCI-sponsored trials are included. For more information, see Volunteering for a Clinical Trial on the their website or talk with your doctor.

NCI Resources on Financial Hardship

Managing Costs and Medical Information: This page discusses the different costs of cancer care and includes practical tips for managing costs.

Financial Toxicity (Financial Distress) and Cancer Treatment (PDQ®): This page highlights research findings and describes factors that may influence a person's risk of financial hardship.

Individuals who are looking for resources in their area can contact NCI's Cancer Information Service or use NCI's searchable database to find local organizations that provide support services.

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