

CENTERS FOR MEDICARE & MEDICAID SERVICES



Medicare and Clinical Research Studies





You have the choice to join a clinical research study to diagnose and treat an illness. If you join a covered clinical research study, Medicare will help pay for some of your costs.

What are clinical research studies?

Clinical research studies (also called clinical trials) may involve diagnostic tests, surgical treatments, medicine, or new types of patient care. These studies may do any of the following:

- Study how well new treatments and tests benefit patients
- Compare different treatments for the same condition to see which treatment is better
- Study new ways to use existing treatments

These studies help doctors, researchers, and patients see if the new care improves patient health.

Should I join a clinical research study?

Before you decide to join a study, it's important to think about the benefits and risks that might be involved.

Benefits may include the following:

- Your health care will be provided by top doctors.
- You will have access to new drugs and treatments before they're widely available.
- Your health care will be monitored closely for any side effects.
- You can take a more active role in your own health care.



Should I join a clinical research study? (continued)

- You may be among the first to benefit if the approach being studied is found to be helpful.
- You will have the chance to make an important contribution to research that may help other people who have the same illness.

Risks may include the following:

- New drugs and treatments may have side effects or risks that your doctors may not know about.
- New drugs and treatments may not be effective, or may be less effective, than current approaches.
- Even if a new approach has benefits, it may not work for you.

Before you agree to take part in a study, someone involved in the study will explain it to you. Then you will be asked to sign an informed consent form. This form describes the clinical research study and what's being tested. It will also explain any possible risks.

Before you sign the form, ask questions so you understand and are comfortable with what will happen during the study. You should feel free to ask any questions or bring up any issues you have about the study at any time.



What is a placebo, and will I be given one?

A placebo is an inactive substance (like a sugar pill) or treatment that looks the same as, and is given the same way as, an active drug or treatment being tested in a clinical research study.

Many clinical research studies compare a new treatment with an existing treatment (a treatment currently known for a disease based on past research). In these studies, patients are randomly put in one group or another. If there isn't an existing treatment, a study may compare a new treatment with a placebo to find out if the new treatment has any effect on the condition being studied. You will be told if you might be given a placebo before you decide whether to take part in the study.

Will I have to pay for any part of the study?

Medicare pays for routine costs of items and services in covered research studies. Examples of these items and services include the following:

- Room and board for a hospital stay that Medicare would pay for even if you weren't in a study
- An operation to implant an item that's being tested
- Treatment of side effects and complications that may occur as a result of the study



Will I have to pay for any part of the study? (continued)

Medicare **won't** pay for the following:

- The new item or service that the study is testing (except for certain medical devices) unless Medicare would cover the item or service even if you weren't in a study
- Items and services the study gives for free (many times the treatment will be provided free by the study sponsor)
- Items or services given only to collect data and not used in your direct health care (such as monthly CT scans for a condition that usually requires only an annual scan)
- Coinsurance and deductibles

I'm in a Medicare health plan. Can I still be in a clinical research study?

Yes. If you're in a Medicare Advantage Plan (like an HMO or PPO) or other Medicare health plan, you can get the same coverage for clinical research studies as a person in Original Medicare, as described in the previous section.

Once you join a Medicare-covered clinical research study, Medicare will pay for your covered services as if you were in Original Medicare. This means that your Medicare health plan can't keep you from joining a clinical research study. However, you should tell your plan before you start a study. That way, the plan can still keep track of your health care services and explain what you will have to pay for copayments, coinsurance, and deductibles.



Will my employer group health plan cover the costs in a clinical research study?

Whether your employer plan covers all or some of the costs depends on the following:

- The rules of your employer plan
- Whether the employer plan or Medicare pays your bills first

Before you join a study, check with your employer plan or your benefits administrator to find out what will be covered. For more information on who pays first, visit www.medicare.gov/Publications/Pubs/pdf/02179.pdf to view the publication “Medicare and Other Health Benefits: Your Guide to Who Pays First.” You can also call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Will my Medigap (Medicare Supplement Insurance) policy pay for my costs if I’m in a clinical research study?

If Medicare covers the routine costs of your study, then your Medigap policy must pay the same as it would for any other Medicare covered services.

However, if Medicare doesn’t cover a certain cost of the study, in most cases your Medigap policy won’t provide any benefits. You should contact the insurance company that provides your Medigap policy for more information.



I'm in a Medicare drug plan (Part D). If I join a clinical research study that tests a prescription drug, will my plan cover the cost of the drug?

Medicare Part B (Medical Insurance) covers a limited number of drugs such as injections you get in a doctor's office, certain oral cancer drugs, drugs used with some types of durable medical equipment (like a nebulizer or infusion pump), and under very limited circumstances, certain drugs you get in a hospital outpatient setting. If the drug isn't covered by Medicare Part B, your Medicare drug plan may cover it. If the drug isn't on your plan's formulary, you can ask your plan for an exception to cover it. However, in most cases, your plan can only cover drugs that have already been approved by the Food and Drug Administration (FDA). Call your plan for more information.

Where can I get more information?

Here's how to find out more about clinical research studies:

- Talk to your doctor.
- Visit www.clinicaltrials.gov. This Web site is a service of the National Institutes of Health (NIH), and it lists government and private studies across the country. It also has more information to help you understand clinical research studies. If you don't have a computer, your local library or senior center may be able to help you find this information.



Where can I get more information? (continued)

To find out about cancer research studies, use the following resources through the National Cancer Institute:

- Call 1-800-4-CANCER (1-800-422-6237) for free cancer information and help finding cancer clinical research studies. TTY users should call 1-800-332-8615.
- Visit www.cancer.gov/clinicaltrials. This Web site lists studies for patients with cancer and detailed information about cancer clinical research studies. If you don't have a computer, your local library or senior center may be able to help you find this information.