

CENTERS FOR MEDICARE & MEDICAID SERVICES



Medicare and Clinical Research Studies





Medicare offers people with Medicare the option to join some clinical research studies for the diagnosis and treatment of illnesses. If you join a covered clinical research study, Medicare will pay some of the patient care costs.

What are clinical research studies?

Clinical research studies (also called **clinical trials**) are one of the final stages of a long and careful research process to help patients live longer, healthier lives. They test new types of medical care, like a new cancer drug. The studies help doctors and researchers see if the new care works and if it is safe. They may also be used to compare different treatments for the same condition to see which treatment is better or to test new uses for existing treatments.

All studies are based on a set of rules called a “protocol.” The protocol tells you the following:

- Who can or can't join the study
- How long the study lasts
- How often you will get tests or medications
- Other details of the study

Why do people join a clinical research study?

People may choose to join a clinical research study for any of these reasons:

- Compare different treatments for the same condition to see which treatment is better.



Why do people join a clinical research study? (continued)

- Test new uses for existing treatments.
- Gain access to new treatments that aren't widely available.
- Obtain medical care from doctors who are leaders in their field of medicine.
- Help future patients with the same illness.

Why do people choose NOT to join a clinical research study?

People may choose not to join a clinical research study for any of these reasons:

- They are concerned about possible risks.
- Some patients don't benefit from the new treatment.
- The study may require more visits to the doctor, or the treatment takes more time than standard care.

Before you agree to take part in a study, a researcher or 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 is being tested. It will also explain any possible risks to you. Before you sign the form, ask questions so you understand and are comfortable with what will happen during the study.



Medicare Payment

What costs does Medicare pay if I'm in a clinical research study?

Medicare pays for routine costs of items and services. 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 is being tested
- Treatment of side effects and complications of the new care

Are there any costs that Medicare won't pay?

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

- The new item or service that the study is testing (except for certain devices) unless Medicare would cover the item or service even if you weren't in a study
- Items and services the study gives you or any participant for free
- Items or services provided only to collect data, and not used in your direct health care (such as monthly CT scans for a condition that usually requires one scan)
- Coinsurance and deductibles



Other Insurance

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

Yes. If you are 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.

You can get your Medicare health care in different ways. You can stay in Original Medicare or choose to join a Medicare Advantage Plan or other Medicare health plan. Original Medicare is a fee-for-service plan that covers many health care services and certain drugs. You pay a set amount each year for your health care (deductible) before Medicare pays its part. Then, Medicare pays its share, and you pay your share (coinsurance or copayment) for covered services and supplies.

Medicare Advantage Plans and other Medicare health plans are plans that may cover more services than those covered by Original Medicare and often have lower out-of-pocket costs. Medicare health plans will have one premium that includes coverage for Part A (Hospital Insurance) and Part B (Medical Insurance) benefits, Part D prescription drug coverage (if offered), and any extra benefits (if offered).



Other Insurance (continued)

Once you join a 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 clinical research study. That way, the plan can still keep track of your health care services. Contact your Medicare health plan to find out what your coinsurance and deductibles would be if you joined a covered clinical research study.

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

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

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

Before you join a study, check with your employer group plan or the benefits administrator to find out what benefits are covered. For more information on who pays first, visit www.medicare.gov on the web and select "Find a Medicare Publication" to look at or print a copy of "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.



Other Insurance (continued)

Will my Medigap (Medicare Supplement Insurance) policy pay for my coinsurance and deductibles if I am in a clinical research study?

If the routine costs of your study are covered by Medicare, then your Medigap policy must pay coinsurance amounts for those costs. If your Medigap policy also covers deductibles and excess charges (the difference between a provider's actual charge and the Medicare-approved payment amount), it must also pay these amounts for routine services.

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

If the drug isn't covered by 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 prescription drugs that have already been approved by the FDA. Contact your Medicare drug plan for more information.



More Information

How can I learn about clinical research studies that might help me?

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

To find out about cancer research studies, use these resources:

- Call 1-800-4-CANCER (1-800-422-6237) for more information. TTY users should call 1-800-332-8615. This toll-free Cancer Information Service provides cancer information and help locating cancer clinical research studies. This is a service of the National Cancer Institute.
- Visit www.cancer.gov/clinicaltrials on the web. This site lists studies for patients with cancer and detailed information about cancer clinical research studies. This site is a service of the National Cancer Institute. If you don't have a personal computer, your local library or senior center may be able to help you find this information.