

Experimental Treatments and Clinical Trials

Most health plans only cover treatments they think are medically proven to work. But, medicine is always changing. Opinions can differ about whether there is enough evidence to support a treatment. In such a case, an insurer may say no to paying for a treatment that it calls “experimental,” even though your doctor thinks the treatment is well supported. That can leave you with a big bill—unless you successfully appeal the insurer’s decision.

In other cases, an experimental, or investigational, treatment may be just what you want. You may have tried standard treatments without success. You may hear of a clinical trial—a study in humans—of a new treatment that has shown promise. You may want to take part in the trial, in hope of getting better. But, how do you learn more about such trials? And, will your insurance cover any of the costs?

This guide will show you:

- How to appeal an insurer’s denial of your claim on the grounds that the treatment is experimental;
- How to find out about clinical trials;
- How to decide whether to enroll in a clinical trial;
- How much you can expect your health insurer to pay for your participation in a clinical trial; and
- What to do if you can’t enroll in a clinical trial but still want an investigational treatment.

Appealing Decisions That a Treatment Is Experimental

If your insurer denies your claim because it says the treatment is experimental, follow your insurer’s appeals process. Also, follow the advice in [Appealing a Reimbursement Decision](#). Get as much information as possible about the decision in writing from the insurer. You’ll want to know how the insurer defines “experimental” and what specific grounds it has for believing your treatment is experimental.

Then, make clear to the insurer in writing why you believe your treatment is not experimental. Support your case as appropriate with a letter from your doctor. There are several kinds of evidence that might be persuasive. Cite journal articles showing that the treatment is safe and effective. Your doctor can detail his or her experience treating patients successfully with the treatment. Cite guidelines recommending the treatment and approvals by the Food and Drug Administration (FDA). Sometimes insurers might use data or documents that are out of date to rule a treatment experimental. If that’s the case here, point that out.

You’ll generally have three chances to appeal. Two phases are internal (appealing to people inside the insurance company) and one external (appealing to people independent of the company). If you need the treatment urgently, ask for an expedited review. That will get your appeal heard faster.



Seeking Clinical Trials

Suppose you've tried current treatments for your disease or condition, and they're not working. Or suppose you've just been diagnosed with a serious disease, such as cancer. You want to know all the options available before you pick one. Then, you might be interested in learning about clinical trials.

The first place to start looking for such a trial is your doctor. Doctors often know about trials that might help you. They may be able to search for one for you. They can also talk over with you the pros and cons of enrolling in a trial. If your regular doctor doesn't help, consider seeking a second opinion.



If you want to look for a trial yourself, try searching [ClinicalTrials.gov](https://www.clinicaltrials.gov), a service of the US National Institutes of Health. Or look for trials on websites associated with the type of disease you have. For example, for cancer, you can try the National Cancer Institute's (NCI's) [database of NCI-supported clinical trials](#).

For each trial you're interested in, read the protocol summary. This document contains such information as the purpose of the trial, the treatments being tested and the locations where the trial is taking place. Much of the information will be in medical language. So, if you're having trouble understanding it, print it

out and take it to your doctor to help you make sense of it.

The key questions to ask when you're reading about a clinical trial include:

- Are you eligible? Read the eligibility criteria, which say who may and may not be part of the trial. Do you have the disease or condition that's being studied? Are you the right age? Does your treatment history match their requirements?
- What is the study's purpose or objective? Does it fit with yours?
- What is the location or locations? Some trials take place in one hospital, others in a number of places. Can you travel to one of those locations? Would you be willing to do so as often as the trial calls for?
- How long will the trial go on? Does that fit with your needs?

Learning More about a Clinical Trial

If you've decided you want to know more, call the trial team at the phone number listed in the protocol summary. Ask for the trial coordinator. If you prefer, have your doctor make the call.

Now, you'll have another set of questions to ask—this time asking the trial team. These questions include:

- Why do you think the treatment you're studying is better than standard treatments? What tests has it already undergone?
- What are the possible risks of the treatment being studied?
- What are the possible benefits?
- How do the risks and benefits of the new treatment compare to those of standard treatments?
- For what costs will the trial pay? (For example, the cost of the treatment; travel expenses.)
- Who'll pay if I'm injured during the trial?
- If the treatment helps me, will I be allowed to keep getting it after the trial is over?

Once you've gotten answers to all your questions, consider whether to enroll. If you decide you will enroll, make an appointment with the trial team.

What Will Your Insurer Pay?

Insurers won't pay for experimental treatment. But, often, the trial sponsor will supply the investigational treatment free of charge. Usually, you'll keep on getting routine care from your own doctor, and your insurer should continue to pay for that.

As for the care you get in the trial setting, current federal law requires most plans to pay for routine patient care costs under certain conditions. For example, you must be eligible for the trial. It must be for treatment of cancer or another life-threatening disease or condition. It must be a federally approved trial. And, it must not involve out-of-network care, unless such care is covered under your plan. If you join an approved trial, most health plans can't limit your benefits or refuse to let you take part.

Health plans don't have to cover the research costs of a clinical trial. That includes extra blood tests done only for research. Often, the trial sponsor will cover such costs.

If you're not sure about what your health plan will pay, check with your plan representative to find out.

If You Can't Get into a Clinical Trial

You may not be able to get into a clinical trial. Perhaps it's because you don't meet eligibility criteria or you live too far away. But, you may still be able to get the treatment under study.

The FDA has an Expanded Access or Compassionate Use program. Through that program, manufacturers make investigational medical products (such as drugs or medical devices) available to people who are seriously ill but can't participate in a clinical trial. The patient must be someone for whom standard approved treatments don't work or can't be used. And, the probable risk from the investigational product can't be greater than the probable risk from the illness. You may have to pay for the product, or the manufacturer may give it free of charge. For more information, see the FDA's [Expanded Access](#) page.

Your Action Plan: Appealing an "Experimental Treatment" Denial; Joining a Clinical Trial

Here are some tips for approaching the subject of experimental treatments and clinical trials:

- If your insurer denies a claim for a standard treatment by calling it "experimental," you can choose to appeal the denial.
- If you want to broaden the options for your care, consider taking part in a clinical trial and getting an investigational treatment.
- Find clinical trials through your doctor or at sites such as [ClinicalTrials.gov](#).
- Read the protocol summary for the trials that interest you. Call the trial team for more information.
- Expect your insurer to pay for routine care costs linked to the trial, assuming certain conditions are met. Don't expect the insurer to pay for the investigational treatment itself or for research costs.
- If you can't get into a clinical trial but are seriously ill, consider the Expanded Access program as a way to get investigational treatments.

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