



Billing for Tests and Procedures When Participating in Research Studies

Frequently Asked Questions for Participants

Mayo Clinic is committed to assuring that all of its research activities involving human subjects are conducted in a way that promotes the rights and welfare of subjects. When considering participation in a research study, billing can be a confusing matter, so we have put together some common research billing questions and answers. Please remember that this is general information and each research study is unique. Before you make a decision about participation, a member of the research team will review the details of the research study with you including the financial aspects of participation.

How will I learn about who will be billed for the costs of a study?

Before you decide if you want to give your consent to participate in a research study, a member of the research team will go over all of the study details with you. This includes explaining how tests and procedures will be billed while you are in the research study.

What costs will be covered by my insurance or Medicare?

Coverage depends on the study and your health insurance plan. Medicare or your insurance typically pay for tests and procedures that are considered “medically necessary.” This determination is made by Medicare or your health care policy. Your insurance provider may have a website that explains what expenses are covered under your plan.

Insurance and Medicare may not pay for all of the charges associated with your participation in a study. If your insurance or Medicare plan does not pay, then you will be responsible for those charges. Check with your insurance or Medicare plan before you consent to be in a research study that involves tests or procedures.

How do I know if a test or procedure is medically necessary?

“Medically necessary” refers to health care services required to diagnose or treat an illness per Medicare or your health insurance policy.

In other words, another patient with your health condition would have the same tests or procedures. The Study Investigator can tell you if you would have the same tests and procedures even if you were not in the study. Confirm with your insurance provider that the test or procedure will be covered under your insurance plan.

What does “Standard of Care” mean? How is it different from “Research Services”?

Standard of care, also known as clinical care, is medical care designed to treat or check on a health condition. In general, all patients with your specific health condition will receive similar medical care. During study participation, some tests or procedures may be standard of care. This means you would have these tests or procedures even if you chose not to participate in the study. When you participate in research, standard of care tests or procedures are billed to you or your insurance unless the study consent form specifically states otherwise. On the other hand, research services are tests or procedures that are done only to collect data for the study. You would not normally have these tests or procedures if you were not in the study. Participants are not billed for research services unless the study consent form states otherwise.

Does it matter if the study is at a site that is in-network or out-of-network for my insurance plan?

Yes, it may. Your insurance plan may not pay for costs of study participation if you choose to be in a study at a site that is out-of-network. Check with your insurance plan to find out if it will pay for out-of-network costs. If needed, ask the study team if the study is being done at another location that is in-network. If you plan to go to another Mayo Clinic site for the study, check with your insurance to confirm what expenses will be covered.

Who should I contact to help with precertification or preauthorization for research tests and procedures?

Ask your Study Team Contact to provide the billing codes for any procedures, labs and tests that may be required for the study. Use these codes when calling your insurance company; let them know these activities may be performed as part of a research study and ask if they will be covered by your insurance plan. The Study Team Contact and Principal Investigator can provide additional resources if precertification or preauthorization is needed. Note: Medicare does not provide preauthorization confirmation, however, they can help you understand whether the tests and procedures are typically considered standard of care.

For studies with an investigational device, who pays for the device and the surgery to implant it?

It depends on the study and type of device. The device and the procedure to put it in your body may be paid for by the study or it may be billed to you/your insurance. The study consent form will state this information.

The Study Team Contact can help with precertification or direct you to precertification resources. It is important to check with your insurance company about your coverage.

For studies where I will receive a drug, who pays for the drug and its administration?

It depends on the study. The study consent form will state if you/your insurance will have to pay for the drug and its administration or if it will be paid for by the study. The study team will review this with you.

Why am I getting billed for a test or procedure that happened during or as a result of a study visit?

The research study may not pay for all tests, exams, and procedures when they are considered standard of care, even if these are done at a study visit. So while test results or other information from a research visit may be collected by the study, sometimes the goal of the visit is to provide the clinical care necessary for patients with this health condition. Clinical care tests or procedures are billed in the normal manner to you or your insurance.

The Study Investigator may tell you results from a test done as part of the research study when it could be useful for your health care.

If other follow-up tests or appointments are needed because of the result of the test, these are considered part of your clinical care. You or your insurance will be billed for these services because they are part of your clinical care and not part of the study. The study does not pay for follow-up tests or appointments that are done for your clinical care.

I became a Mayo Clinic patient specifically to participate in this study. Why am I getting billed for my first appointment with the Study Investigator?

As a new patient, you may have a physical exam at your first research appointment. Even though this physical exam is done at a research appointment, it may be considered clinical care. A physical exam that qualifies as clinical care will be billed to you or your insurance.

What do I do if I think I have been billed incorrectly for research tests or procedures?

Each informed consent document includes the phone number for billing questions. When you call Patient Account Services, have your Mayo Clinic number available and tell them that you think you were billed for a research service. Patient Account Services will ask Research Post Award Compliance and the Study Team Contact or Principal Investigator to review your bill. It may take several weeks to review your bill. If you were billed in error, your account will be fixed, and you or your insurance will be refunded any money that was paid. It can take up to two billing cycles (2 months) for your billing statement to show this change.

Do I have to pay my deductible and copays if I am participating in a study?

Yes. If your insurance company is being billed, then you will need to pay your deductible, copays, and coinsurance fees.

Who pays for costs of treatment if I am injured or receive care for side effects related to study participation?

Research-related injuries and side effects are different. All study consent forms have a section called "What if you are injured from your participation in this research study?" This section will tell you how your study handles this situation. You should promptly notify the Principal Investigator if you think you have suffered a research-related injury. Side effects possibly related to study participation (for example, study drugs, devices, procedures, activities, etc) are risks typically listed in the consent form, however, some side effects may not be known. The treatment of side effects is considered to be clinical care and the associated costs will be billed to you or your insurance, unless otherwise noted on the study consent form.

Who should I contact at Mayo Clinic if I have additional questions about study billing?

The Study Team Contact or Principal Investigator (listed on the consent form) are available to answer your questions. When necessary, they will refer you to other staff that can help.

Mayo Clinic Billing Contacts

Patient Account Services: 844-217-9591

Note: This number serves all Mayo locations; regular business hours are 7 am–6 pm CST, Monday through Friday, excluding holidays.