BILLING FOR TESTS AND PROCEDURES WHEN PARTICIPATING IN RESEARCH STUDIES
FAQs for Participants

There is a financial cost to doing research. All aspects of a research study, including tests and procedures, are billed to either the study, a study participant’s health insurance company, Medicare, or the study participant. For most studies, the patient and/or their insurance will be billed for tests and procedures that represent the “standard of care” designed to diagnose, treat, or monitor your health problems. These services would be provided to you even if you are not participating in a clinical research study. A member of the research team will go over the details of your particular study with you before you decide if you want to join the study.

This can be a confusing topic, so we have put together some common research billing questions and answers. Please note this is general information, and each research study is unique.

HOW WILL I LEARN ABOUT WHO WILL BE BILLED FOR THE COSTS OF A STUDY?
A member of the research team will go over the study details with you before you decide if you want to join the study. The team member will tell you how tests and procedures will be paid for while you are in that research study.

WHAT COSTS WILL BE COVERED BY MY INSURANCE OR MEDICARE?
It depends on the study and your health insurance plan. Insurance and Medicare may not pay for all costs for participant care in a study. Your insurance plan may have a website that explains what it will pay for. Medicare or your insurance will usually pay for tests and procedures that are “medically necessary.” This determination is made by Medicare or your healthcare policy. Medicare has a list of covered services that can be found here: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

If your insurance or Medicare plan will not pay, then you will have to pay for those costs. Check with your insurance or Medicare plan before you choose 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 to diagnose or treat an illness per Medicare or your health insurance policy. In other words, another patient with your health problem would have the same tests and procedures. The study investigator can tell you if you would have the same tests and procedures even if you were not in the study. Check with your insurance to find out if the test, procedure or treatment plan will be paid.

WHAT DOES “STANDARD OF CARE” MEAN? HOW IS IT DIFFERENT FROM RESEARCH?
Standard of care is medical care designed to treat or check on your health problem. In general, all patients with your health problem will receive similar medical care. Some tests or procedures that are part of your study participation may be standard of care. You would have these tests or procedures even if you were not in the study. You or your insurance will be billed for tests or procedures that are standard of care unless the study consent form states otherwise. In contrast, 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. You will not be 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 site that is in-network. If you plan to go to another Mayo Clinic site for the study, check with your insurance first to see if it is still in-network.
**Who should I contact to help with precertification or preauthorization for research tests and procedures?**

Ask your Study Team Contact or Principal Investigator. They can direct you to the staff that can help you with this process. Also, check with your insurance company to learn more about your precertification status and coverage.

**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 billed for by the study or it may be billed to you/your insurance. The study consent form will state this information. This Medicare website lists device studies that are covered by Medicare: https://www.cms.gov/Medicare/Coverage/IDE/index.html.

Ask your Study Team Contact or Principal Investigator for help with precertification. 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.

**Why am I getting billed for a test or procedure that happened at a study visit?**

The research study may not pay for all tests, exams, and procedures, even if these are done at a study visit because they are considered standard of care tests or procedures. Sometimes the goal of the study visit is to give you clinical care that patients with your health condition often get. Test results or other information from this visit may be used for the study.

**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. Because it is clinical care, this physical exam is billed to you or your insurance.

**What do I do if I think I’ve been billed incorrectly for research tests or procedures?**

Call Patient Account Services (phone numbers found in the study consent form under “Contacts, Research Billing”) and tell them that you think you were billed for a research service. Patient Account Services will ask Research Finance 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’m participating in a study?**

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

The study investigator may tell you results from a test done as part of the research study because 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 will not pay for follow-up tests or appointments that are done for your clinical care.

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

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.

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

Call the Study Team Contact or Principal Investigator (found on the second page of your consent form). They can help you or refer you to other staff that can help you.

**Where can I learn more about Medicare coverage and research participation?**


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**Mayo Clinic Billing Contacts**

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<tr>
<th>Location</th>
<th>Phone Numbers</th>
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<tbody>
<tr>
<td>Rochester, MN</td>
<td>507-266-5670 (toll free) 1-800-660-4582</td>
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<tr>
<td></td>
<td>Florida: 904-953-7058 (toll free) 1-800-660-4190</td>
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<td></td>
<td>Arizona: 480-301-7033 (toll free) 1-800-603-0558</td>
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<tr>
<td>Albert Lea, MN</td>
<td>1-855-587-6487</td>
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<tr>
<td>Mankato, MN</td>
<td>1-855-587-6487</td>
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