

INSURANCE BILLING AND CLINICAL TRIALS

As part of your participation in a clinical trial, we want to ensure that you have a good understanding of the billing process for research claims and what is expected of you.

The Informed Consent and the Study team

The informed consent form will have a section titled “Costs to You” or similarly titled section. This section will contain information specific to the clinical trial in which you are enrolling and should tell you what will be paid for by the study. You will receive a copy of the informed consent form for you to keep as a reference. In addition, the study team is available to help you understand what is paid for and provided by the study and what expenses may be the responsibility of you or your insurer. Do not hesitate to ask if you have any questions.

Insurance Billing

Sometimes the research study will pay for all of the costs associated with the clinical trial. More often, services that would have been performed for your disease or condition as a regular patient who is not in a research study will be billed to your insurance company. This means that you will be responsible for any deductibles, copays, and coinsurance required by your insurance company. In certain circumstances, the Affordable Care Act allows for payment of the routine costs of clinical trials by insurance companies and protects you from having any claims denied solely due to your participation in a trial. Keep in mind that insurance companies can determine for each plan what is and is not a covered benefit and may require notification or pre-authorization. It is important that you understand your plan benefits and reach out to your insurance company with any questions.

Medicare and Medicare Advantage Plans

Medicare pays for the routine costs of items and services for patients enrolled in qualifying clinical trials. As with commercial insurance, you will be responsible for any applicable deductibles, copays, and coinsurance.

If you are enrolled in a Medicare Advantage Plan, your health care bills for the routine costs in the clinical trial will be sent to Medicare first. This may result in a higher copay. The copay should then be directed to your Medicare Advantage Plan for reimbursement to you. Device trials will be paid by your Medicare Advantage Plan as the primary insurance.

Billing Issues or questions

During the study it is important for you to review the Explanation of Benefits provided to you by your insurance company and to check any bills you may receive for your care. If you think you or your insurance company were billed for something that should have been paid for by the study, reach out to your study coordinator so we can double check and correct any errors. If you receive a denial for a claim from your insurance company, please bring your explanation of benefits to your study coordinator.

If you are having trouble paying your medical bills, please reach out to the financial aid office at 801-587-6303 or online at <https://healthcare.utah.edu/bill/#financialassistance>.

ADDITIONAL RESOURCES FOR COSTS IN CLINICAL TRIALS

Medicare and Clinical Research Studies

<https://www.medicare.gov/Pubs/pdf/02226-Medicare-and-Clinical-Research-Studies.pdf>

National Institutes of Health (NIH)- Questions to ask before enrolling- Cost issues

<https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>

NIH/National Cancer Institute- Insurance Coverage and Clinical Trials: Paying for Clinical Trials

<https://www.cancer.gov/about-cancer/treatment/clinical-trials/paying/insurance>

ASCO- Cancer.net

<https://www.cancer.net/research-and-advocacy/clinical-trials/health-insurance-coverage-clinical-trials>

National Comprehensive Cancer Network (NCCN)- Financial assistance and support for specific cancer drugs

https://www.nccn.org/professionals/meetings/oncology_policy_program/pdf/vrrr_guide-case_managers.pdf

Patient Advocate Foundation- Insurance Factors to Consider with Clinical Trials

<https://www.patientadvocate.org/explore-our-resources/understanding-health-insurance/insurance-factors-to-consider-with-clinical-trials/>

University of Utah Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu regarding concerns or complaints about the study.

Institutional Review Board: Contact the Institutional Review Board if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by email at irb@hsc.utah.edu.