

Clinical Trials and Insurance Coverage

Understanding Out of Pocket Cost for Clinical Trial Participation

As you think about participating in a clinical trial, you will face the issue of how to cover the costs of care. Even if you have health insurance, your plan may not cover all expenses related to your participation on the clinical trial and management of your care. It is important for you to understand the costs and the portions that may be your responsibility.

Cost Associated with Clinical Trials and Who Pays for Them

There are two types of costs related to a clinical trial:

1. Patient Care Costs
2. Research Costs.

Patient care costs, also referred to as, **standard of care costs**, are those related to treating your cancer. These costs apply whether you are in a clinical trial or receiving standard of care therapy. These costs are billed to your health insurance even though you are on a clinical trial. You may be responsible for the deductible amount and co-pays as outlined in your health insurance policy. Any co-pays required will be collected when you check in for your appointment.

Some examples of patient care/ standard of care costs:

- Certain diagnostics tests (x-rays, blood work, etc)
- Supportive medications used to manage symptoms like pain or nausea
- Supportive medications used to manage changes in the blood counts
- IV fluids for dehydration

Research costs are those associated with taking part in a clinical trial. These costs might include extra tests or procedures that you need as a part of the trial, but not part of your routine care. These costs are not covered by health insurance. At Mary Crowley Cancer Research, we work closely with the companies (pharmaceutical, and etc.) that sponsor the clinical trials to ensure their budget pays for all research related tests or procedures.

Some examples of research costs:

- Investigational therapy
- Test conducted specifically for the purpose of research.

Patient Care Costs / Standard of Care	Research Costs
Physician Visits	Physician and nurse time related specifically to research
Hospital Stays	Analysis of research results
Lab Tests	Clinical tests performed purely for research purposes
X-rays and Scans	Investigational therapy/drug
Standard of Care Drugs	
Supportive Care Medications	

Understanding Your Health Insurance for Clinical Trials

Before you enroll:

Speak with the Financial Counselor to see if participation will be covered and to what extent. Learn which costs may be your responsibility.

Understanding Out of Pocket Cost of Participation in Clinical Trials

If your insurance company is refusing to cover the cost of the clinical trial, you can appeal with:

- Medical journal articles that show patient benefits of the clinical trials
- A letter of medical necessity
- Researcher's explanation of the clinical trial

Some states have laws or special agreements that require health insurance companies to pay for routine care you receive in a clinical trial. In Texas, Senate Bill 39 (Chapter 719) effective September 1, 2009, mandates coverage for routine care costs of clinical trials.

During your participation on a Clinical Trial:

Review all Explanation of Benefits from your insurance company to ensure claims are being filed and paid correctly. If not, speak to the Financial Counselor as soon as you discover an error.

Non-research related expenses might be billed to your insurance. For example: IV fluids, additional x-rays, or supportive medications.

Work closely with the Patient Coordinator or Clinical Research Nurse to provide information required by the insurance company.

Helpful hints:

- Keep a copy of the material(s) sent to the insurance company.
- Enlist the help of the key contacts noted below to work with your insurance company to learn:
 - If routine patient care is covered in your policy while you participate in a clinical trial.
 - If an authorization is required (verify which procedures, medications, tests, etc. require authorization).
- Many insurance companies offer an Oncology Nurse Case Manager who serves as a patient advocate to obtain needed services.
- Understand all the costs related to your participation on the clinical trial (insurance costs, research costs, out of pocket patient care costs).
- Your employer's benefits manager may be a resource for working with the insurance company.
- If your claim is denied, contact the key contacts noted below to assist you in filing an appeal.

Dealing with financial issues can be challenging when you or a loved one faces cancer. For more information and resources for dealing with finances related to your cancer, visit the:

- National Cancer Institute www.cancer.gov.
- American Cancer Society www.cancer.org.
- Livestrong Foundation www.livestrong.org.

Key contacts at the Mary Crowley Cancer Research

Title	Name	Contact Information
Financial Counselor		
Patient Coordinator		
Clinical Research Nurse		