

Clinical Trials and Insurance Coverage

Understanding Out of Pocket Cost for Clinical Trial Participation

As you think about participating in a clinical trial, it is important for you to understand the costs and the portions that may be your responsibility. 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.

Costs 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 or routine 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 diagnostic tests (x-rays, blood work, etc)
- Supportive medications used to manage symptoms like pain or nausea
- Supportive medications used to manage changes in your lab values
- 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 that sponsor the clinical trials to ensure their budget pays for all research related tests or procedures.

Some examples of research costs:

- Investigational agent/drug
- Tests conducted specifically for the purpose of research

Patient Care Costs / Standard of Care	Research Costs
Provider Visits	Provider and nurse time related specifically to research
Hospital Stays Related to Your Disease	Analysis of research results
Lab Tests	Clinical tests performed purely for research purposes
X-rays and Scans	Investigational agent/drug
Standard of Care Drugs	
Supportive Care Medications (IV Fluids, medications to help deal with side effects)	

Understanding Your Health Insurance for Clinical Trials

Before you enroll:

Our Financial Counselor will speak with you to advise of the following:

- If your health insurance plans are in network
- If your health insurance plans cover standard of care while on a clinical trial

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- Your specific patient responsibility based on your insurance plan for co pays, deductibles, etc.
- If your health plan requires a Primary Care Provider referral

If your insurance company is refusing to cover the cost of the clinical trial, we can appeal on your behalf 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 while enrolled 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 your Study Coordinator or Clinical Research Nurse to provide information required by the insurance company.

Helpful hints:

- Many insurance companies offer an Oncology Nurse Case Manager who serves as a patient advocate to obtain needed services.
- Your employer's benefits manager may be a resource for working with the insurance company.
- The amount each individual patient will have to pay depends on each patient's insurance plan. Each plan will typically have a deductible, co pay, co-insurance and out of pocket max that the patient must meet to determine potential cost. Below you will find a brief explanation of these terms

Insurance Term	Definition
Deductible	The amount a patient pays for covered health services before insurance will begin to pay.
Co-Pay	A fixed amount paid by the patient for covered services.
Co-Insurance	A percentage of money that the patient begins to pay typically after you have met the deductible.
Out of Pocket Max	Is a cap or a limit to how much you pay for the year before insurance covers you at 100%

Dealing with financial issues can be challenging when you or a loved one faces cancer. You can request to speak to the clinic Social Worker if you would prefer to discuss your situation or explore resources.