Health Insurance Coverage of Clinical Trials

How are clinical trials covered?
The Patient Protection and Affordable Care Act (ACA) is a law that affects the cost of and access to medical care. This law includes regulations regarding the coverage of clinical trials.

The ACA states that health plans or insurers can’t keep patients from joining a clinical trial or increase costs because a patient joins a clinical trial. In addition, they can’t limit or deny coverage of routine costs to patients who choose to join an approved clinical trial.

Are there health plans that do not provide coverage?
The clinical trials coverage provision doesn’t apply to a “grandfathered” health plan. This is a plan that existed on or before the ACA went into effect on January 1, 2014. However, if the plan reduces benefits or raises costs, the government may no longer consider it a grandfathered plan. This means the plan must follow all ACA requirements, including covering routine clinical trials costs. If you do not know if your plan is considered a grandfathered plan, contact your health insurance provider.

What costs are covered?
If the ACA requirements apply to your health plan, your insurer must cover routine costs. Routine costs include office visits, lab tests, supportive care drugs, and procedures or services you need while you’re in the trial. These are the costs your insurer would cover even if you weren’t in the trial.

Medicare has slightly different rules for covering clinical trials. This includes drugs, procedures, and services that would be covered outside of the clinical trial. It also includes care needed to receive the treatment and care for any side effects.

The government does not require Medicaid to cover clinical trials. But, some states will cover clinical trials through Medicaid.

What costs are not covered?
Health insurers and Medicare don’t have to cover the research costs of the clinical trial. These are the costs of the treatment being studied and any procedure needed to collect data. However, many clinical trial sponsors cover these costs. Some may also cover transportation, childcare, meals, and places to stay. Talk with the research team to find out what is and isn’t covered.
Questions to ask a clinical trial’s research team
Before participating in a clinical trial, consider asking the research team the following questions about clinical trial costs:

- Who is sponsoring or funding this clinical trial?
- What costs are associated with this clinical trial?
- Which of these costs are covered by the clinical trial sponsor?
- Can you help me find out what costs will be covered by my insurance?
- Which costs will I be responsible for?

Find additional questions related to clinical trials at www.cancer.net/clinicaltrials and questions on the cost of care and the ACA at www.cancer.net/managingcostofcare.

Where to find additional information
Several governmental organizations can help you understand required health care coverage:

- Center for Consumer Information and Insurance Oversight (www.cms.gov/cciio)
- State Insurance Departments (www.medicare.gov/contacts)
- U.S. Department of Labor (www.askebsa.dol.gov)

Other organizations to help you understand how these health insurance requirements affect your care:

- Patient Advocate Foundation (www.patientadvocate.org)
- CancerCare (www.cancercare.org)
- Cancer Support Community (www.cancersupportcommunity.org)

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