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## **Health Insurance Coverage of Clinical Trials [1]**

This section has been reviewed and approved by the [Cancer.Net Editorial Board](#) [2], 01/2014

### **Key Messages:**

- The Affordable Care Act (ACA) requires health insurance companies to cover routine costs associated with approved clinical trials.
- Health insurance companies are not required to cover the cost of the treatment or procedure being researched; however, the clinical trial's sponsor may cover these costs.
- Talk with your doctor and the clinical trial research team to learn what costs will be covered and what costs you will be expected to pay.

### **Understanding the costs covered by insurance**

In March 2010, the Patient Protection and Affordable Care Act, often called "health care reform" or the "ACA," was signed into law, changing several rules regarding health care insurance coverage in the United States, including coverage of clinical trials. As part of the ACA, health plans or insurers cannot deny patients' participation in a clinical trial, limit or deny coverage of routine costs to patients who choose to participate in an approved clinical trial, or increase costs because a patient chooses to participate in a clinical trial. This means that your insurer cannot limit your benefits if you choose to enroll in a clinical trial.

This law does not apply to a "grandfathered" plan, which is a health plan that existed on March 23, 2010 (when the ACA was signed into law). However, if this plan reduces its benefits or increases its costs, it may no longer be considered a grandfathered plan and must follow all ACA requirements, including covering the routine costs of clinical trials. A grandfathered plan must notify you of its grandfathered status in all informational materials that describe your plan benefits. To find out if you are enrolled in a grandfathered plan, contact the Employee Benefits Security Administration, U.S. Department of Labor at [www.askebsa.dol.gov](http://www.askebsa.dol.gov) [3] or 866-444-3272. If it is a state-regulated plan, you can contact your [state insurance regulatory agency](#) [4].

### **Approved clinical trials**

An approved clinical trial is a study being done for the prevention, detection, or treatment of cancer or another life-threatening illness. According to the law, the clinical trial must be federally

funded, have an investigational new drug (IND) application, or be exempt from IND requirements. These three criteria are described below in more detail. However, your doctor or the study sponsor can tell you if the clinical trial you are considering is covered by the ACA.

**Federally funded.** This means the clinical trial is approved or funded by one or more of the organizations listed below.

- National Institutes of Health (which includes organizations under NIH, such as the National Cancer Institute, NCI) and organizations funded by the NIH or NCI (such as academic institutions, designated cancer centers, and cooperative groups)
- Centers for Disease Control and Prevention (CDC)
- Agency for Health Care Research and Quality (AHRQ)
- Centers for Medicare and Medicaid Services (CMS)
- Department of Defense, Department of Veterans Affairs, or the Department of Energy if the trial is subject to unbiased, scientific review by experts that is similar to NIH requirements

**Has an IND application.** Researchers must submit an IND application to the U.S. Food and Drug Administration (FDA) in many instances to give the drug in clinical trials. Your doctor or the sponsor of the clinical trial will be able to tell you if this study has an IND requirement.

**Is exempt from IND application requirements.** In certain situations, researchers do not need to request permission from the FDA to study an approved drug or treatment. This occurs when the research is not being done to request FDA approval for such changes as changing the drug's labeling, advertising a new use, or testing a new dosage or way to give the drug.

### **Routine Costs and Choice of Provider**

If you choose to join a clinical trial that falls under the ACA requirements, your insurer must provide coverage for routine costs. Routine costs include any drugs, procedures, and/or services you need while participating in the trial that your insurer would normally cover, even if you were not participating in the trial. Your insurer is not required to cover anything outside of the routine costs (often called the research costs), which includes the treatment or procedure being studied, any procedure done only to collect data for the study, and anything that is not related to the standard treatment for your condition. However, these research costs are often covered by the trial's sponsor.

Your health insurance provider may also require you to visit a doctor or hospital who participates in your health plan's network, called an in-network provider. The insurance materials should include a list of these providers. However, if your plan includes coverage for out-of-network services, which are doctors and hospitals that are not listed as part of the insurance network, the insurer must cover your routine costs of care for an out-of-network clinical trial.

### **Medicare and Medicaid coverage for clinical trials**

**Medicare.** The ACA does not affect Medicare coverage of clinical trials. Medicare already covers the routine costs related to clinical trials and will continue to cover these costs. Medicare covers the following costs associated with a clinical trial:

- Any drugs, procedures, and services you need while participating on the trial that would normally be covered through Medicare, even if you were not participating in the trial.
- Medical care needed to give the treatment being studied; (For example, care related to the actual administration of chemotherapy would be covered, but the drug may not be.)
- Medical care related to any health complications from the clinical trial, such as the prevention and management of side effects

Medicare does not cover any research-related costs. There are special rules for people enrolled in Medicare managed care plans (called Medicare Advantage plans). If you are enrolled in a Medicare managed care plan, traditional Medicare coverage provides coverage of the routine patient costs of a clinical trial. The Medicare managed care plan pays any difference between your out-of-pocket costs in traditional Medicare and your out-of-pocket costs in your Medicare managed care plan.

**Medicaid.** The ACA clinical trials coverage provision does not apply to Medicaid plans. Federal law does not require that states provide coverage of clinical trials through the Medicaid program, although states may have laws that require Medicaid to cover clinical trials. ASCO supports [legislative initiatives \[5\]](#) that promote access to clinical trials under Medicaid.

### **Costs not covered by health insurance**

Because health insurance companies and Medicare are not required to provide coverage for the cost of the treatment or procedure being studied, or any procedure only needed to collect data for the study, it is important to know which costs you will be responsible for paying. Many clinical trial sponsors may provide the treatment or procedure being studied for free, as well as cover the cost of tests needed for data collection. Some may also reimburse for expenses associated with participating in the research, such as transportation, childcare, meals, and accommodations. However, the treatments, tests, and procedures provided for free vary, depending on the trial. It is important to talk with the clinical trial research team about what may not be covered. Generally, you will discuss this with the research team during the process of [informed consent \[6\]](#), but you may want to consider asking specific questions about the costs of the clinical trial before enrolling in the trial.

### **For more information**

[ASCO Answers Fact Sheet - Clinical Trials Coverage Through the Affordable Care Act \[7\]](#)

[Managing the Cost of Cancer Care \[8\]](#)

[Questions to Ask the Research Team \[9\]](#)

[Clinical Trials \[10\]](#)

[Insurance Coverage for Clinical Trial Participants \[11\]](#)

### **Additional Resources**

[HealthCare.gov \[12\]](#)

Centers for Medicare & Medicaid Services [13]

U.S. Department of Labor [14]

ClinicalTrials.gov [15]

Patient Advocate Foundation [16]

CancerCare [17]

Cancer Support Community [18]

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**Links:**

[1] <http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/health-insurance-coverage-clinical-trials>

[2] <http://www.cancer.net/about-us>

[3] <http://www.askebsa.dol.gov>

[4] <http://www.medicare.gov/Contacts/staticpages/sids.aspx>

[5] <http://jco.ascopubs.org/content/29/28/3816.full>

[6] <http://www.cancer.net/node/24879>

[7] [http://www.cancer.net/sites/cancer.net/files/clinical\\_trials\\_coverage\\_aca\\_fact\\_sheet.pdf](http://www.cancer.net/sites/cancer.net/files/clinical_trials_coverage_aca_fact_sheet.pdf)

[8] <http://www.cancer.net/node/24865>

[9] <http://www.cancer.net/node/24881>

[10] <http://www.cancer.net/node/24863>

[11] <http://www.asco.org/practice-research/insurance-coverage-clinical-trial-participants>

[12] <http://www.healthcare.gov/>

[13] <http://www.cms.gov/>

[14] <http://www.dol.gov/>

[15] <http://clinicaltrials.gov/>

[16] <http://www.patientadvocate.org/>

[17] <http://www.cancercare.org/>

[18] <http://www.cancersupportcommunity.org/>