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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], 03/2016

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

The Patient Protection and Affordable Care Act (ACA) is a law that affects the cost of and access to medical care. Another name for the ACA is health care reform. Included in this law, are regulations regarding the coverage of clinical trials. Specifically, the ACA states that health plans or insurers can't:

- Keep patients from joining a clinical trial
- Limit or deny coverage of routine costs to patients who choose to join an approved clinical trial
- Increase costs because a patient chooses to join a clinical trial

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. However, if the plan reduces benefits or raises costs, the government may no longer consider it a grandfathered plan. Losing grandfathered status means the plan must follow all ACA requirements, including covering routine clinical trials costs. A grandfathered plan must note its grandfathered status in materials that describe the plan benefits. If you do not know if your plan is considered a grandfathered

plan, contact your health insurance provider.

## Approved clinical trials

The law applies to clinical trials designed to study new methods to prevent, detect, or treat cancer or another life-threatening illness. According to the law, an approved clinical trial must:

- **Be federally funded.** This means one or more of the organizations listed below approved or funded the clinical trial.
  - National Institutes of Health (NIH), including organizations under NIH such as the National Cancer Institute (NCI)
  - Organizations funded by the NIH or NCI, including academic institutions, designated cancer centers and cooperative groups
  - Centers for Disease Control and Prevention (CDC)
  - Agency for Health Care Research and Quality (ARHQ)
  - Center for Medicare and Medicaid Services (CMS)
  - Department of Defense, Department of Veteran Affairs, or the Department of Energy, if the trial is subject to unbiased, scientific review that's similar to NIH requirements
- **Have an investigational new drug application.** Researchers often must submit an investigational new drug application to the U.S. Food and Drug Administration (FDA). They need FDA approval to provide a drug that is still under development in a clinical trial. Your doctor or the clinical trial sponsor can tell you if the study has approval for an investigational new drug.
- **Be excused from investigational new drug application requirements.** Sometimes, researchers don't need to ask the FDA for permission. This occurs when doctors aren't seeking FDA approval for a new use of an existing drug. But, researchers still need the FDA to approve changes to a drug's labeling or advertising. Researchers also need FDA approval to test a new dosage or way to give the drug because it could increase risk for the people participating.

Your doctor can help determine if the ACA covers the clinical trial you're considering.

## **Routine costs and choice of provider**

If you choose to join a clinical trial and the ACA requirements apply to your insurance plan, your insurer must cover routine costs. Some examples of routine costs are:

- Office visits
- Lab tests
- Supportive care drugs
- Procedures and/or services you need while you're in the trial

These are costs your insurer would cover even if you weren't in the trial. However, your insurer doesn't have to cover the treatment being studied (see Costs not covered, below).

Your insurer may also not cover providers that are outside your health plan's network. The insurance materials should list the providers covered by your plan. Sometimes an insurance plan includes coverage for out-of-network providers. These are doctors and hospitals that the insurer doesn't list as part of its network. If you have out-of-network coverage, 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 doesn't affect Medicare coverage of clinical trials. Medicare has slightly different rules for covering clinical trials. Medicare covers the following routine clinical trial costs:

- Drugs, procedures, and services that Medicare would cover if you weren't enrolled in the clinical trial.
- Medical care you need to get the treatment the trial is studying. For example, Medicare would cover care related to chemotherapy administration but not the new chemotherapy drug being studied.
- Medical care related to any health complications from the clinical trial. One example is the prevention and management of side effects.

There are special rules for people enrolled in Medicare-managed care plans, also called Medicare Advantage plans. If you're in one of these plans, traditional Medicare covers routine clinical trial patient costs. Then the Medicare Advantage plan pays any difference in out-of-pocket costs between traditional Medicare and your Medicare Advantage plan.

Medicare doesn't cover research-related costs.

**Medicaid.** The ACA clinical trials coverage rule doesn't apply to Medicaid plans. Federal law doesn't require states to cover clinical trials through Medicaid. However, some states have laws that require Medicaid to cover clinical trials.

## Costs not covered by health insurance

It's important to know which costs you'll have to pay before you join a clinical trial. Remember, health insurance companies and Medicare don't have to cover:

- The cost of the treatment or procedure the trial is studying
- Any procedure only needed to collect data for the study

However, many clinical trial sponsors cover those costs. Some also may cover expenses such as transportation, childcare, meals, and places to stay.

What's free differs for each trial. Talk with the clinical trial research team about what it will and won't cover. And, check to see whether your insurance plan must meet the ACA clinical trial coverage requirements. You'll usually talk about this with the team during the [informed consent](#) [3] process.

## More Information

[ASCO Answers Fact Sheet: Clinical Trials Coverage Through the Affordable Care Act](#) [4]

[Financial Considerations](#) [5]

[Questions to Ask the Research Team](#) [6]

[Insurance Coverage for Clinical Trial Participants](#) [7]

## Additional Resources

[HealthCare.gov](#) [8]

[Centers for Medicare & Medicaid Services](#) [9]

[U.S. Department of Labor](#) [10]

[Patient Advocate Foundation](#) [11]

[CancerCare](#) [12]

[Cancer Support Community](#) [13]

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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.cancer.net/node/24879>
- [4] [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)
- [5] <http://www.cancer.net/node/24865>
- [6] <http://www.cancer.net/node/24881>
- [7] <http://www.asco.org/insurance-coverage-clinical-trial-participants>
- [8] <http://www.healthcare.gov/>
- [9] <http://www.cms.gov/>
- [10] <http://www.dol.gov/>
- [11] <http://www.patientadvocate.org/>
- [12] <http://www.cancercare.org/>
- [13] <http://www.cancersupportcommunity.org/>