

ASCO ANSWERS

CLINICAL TRIALS COVERAGE THROUGH THE AFFORDABLE CARE ACT

WHAT IS THE AFFORDABLE CARE ACT?

The Patient Protection and Affordable Care Act (ACA), signed into law March 2010, changed several rules about health care insurance coverage in the United States, including coverage of clinical trials. Clinical trials study new ways to treat, prevent, or diagnose cancer, manage side effects, or improve patients' quality of life. They often offer treatment options that would not otherwise be available outside of the clinical trial.

HOW ARE CLINICAL TRIALS COVERED THROUGH THE ACA?

The ACA sets the national minimum for coverage of clinical trials. Health plans newly issued or renewed on or after January 1, 2014, will not be allowed to limit or deny your coverage if you choose to participate in an approved clinical trial. This requirement applies to group health plans offered by your employer and plans purchased from an insurance company through an ACA insurance exchange. If your state has a law requiring more coverage, your insurer will continue to follow those requirements in addition to the ACA requirements.



Find additional cancer information at www.cancer.net.

WHICH HEALTH PLANS DO NOT FOLLOW THE ACA REQUIREMENTS FOR CLINICAL TRIALS COVERAGE?

The ACA clinical trial coverage provision does not apply to a “grandfathered” plan, which is a health plan that existed when the ACA was signed into law. Some grandfathered plans may already cover clinical trials. If your grandfathered insurance plan has reduced benefits or increased costs since March 23, 2010, or does so in the future, it is no longer a grandfathered plan. Then, it will need to follow all ACA requirements, including the clinical trials coverage requirement. A grandfathered plan must notify you of its grandfathered status in all informational materials that describe your plan benefits.

WHAT COSTS DOES THE ACA REQUIRE MY HEALTH INSURANCE TO COVER?

Your insurer must provide coverage for routine costs of care. Routine costs of care include any treatments, procedures, and services you need while participating in the clinical trial that would normally be covered if you were not participating in a trial. The ACA does not require your insurer to cover the research costs for the clinical trial. These may include the drug being studied and any treatments, tests, or procedures done to collect data for the study. These research costs are not usually considered part of the standard care for your condition, but they are often covered by the clinical trial sponsor.

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/managingthecostofcare.

WHERE TO FIND ADDITIONAL INFORMATION

Several governmental organizations can help you understand required health care coverage:

- Center for Consumer Information and Insurance Oversight (www.healthcare.gov)
- State Insurance Departments (www.medicare.gov/Contacts/staticpages/sids.aspx)
- 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)



Doctor-Approved Patient Information from ASCO®

For more information, visit ASCO's patient website, www.cancer.net, or call 888-651-3038.

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A central IRB has determined that this information is not research and can be distributed to patients considering participation or already participating in a clinical trial.

TERMS TO KNOW

Approved clinical trial:

A study that is done to help prevent, detect, or treat cancer or another life-threatening disease and is federally funded, conducted under an IND, or exempt from having an IND application

Health Care Reform:

A common term for the Affordable Care Act

Investigational New

Drug (IND) application:

Researchers must submit an IND application to the U.S. Food and Drug Administration (FDA) to get approval to sell new drugs or treatments

Health Insurance

Exchange/Marketplace:

HealthCare.gov is where a person can purchase a state-specific health plan that must follow the ACA requirements. These plans are referred to as "exchanges." Some states operate their own exchanges, and if you live in one of these states, you can contact your state agency for more information

Research costs:

The treatment or procedure being studied or any tests or procedures needed to collect data for the clinical trial; these costs are often paid for by the trial sponsor

Routine costs:

Any item or service for your care that would normally be covered if a patient is not in a clinical trial

Sponsor:

The company or organization that funds a clinical trial