October 2013

The Affordable Care Act:

Clinical Trials Coverage

BlueCross BlueShield of Illinois

Frequently Asked Questions

We have had a number of questions requesting details about the clinical trials provision, and we want to provide additional information about the mandate by sharing some of the more frequently asked questions.

Q **What is a qualified individual according to the Affordable Care Act (ACA)?**

A A qualified individual is someone who is eligible to participate in an approved clinical trial based on either of the following:

- The individual's health care provider has concluded that participation is appropriate.
- The participant provides medical and scientific information establishing that his or her participation is appropriate according to the trial protocol with respect to the treatment of cancer or other life-threatening condition.

Q **What is an approved clinical trial according to ACA?**

A An approved clinical trial is defined as a Phase I, II, III or IV clinical trial for the prevention, detection or treatment of cancer or other **life-threatening condition** or disease (or other condition described in ACA, such as federally funded trials, trials conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration or drug trials exempt from having an investigational new drug application). **A life-threatening condition** is any disease from which the likelihood of death is probable, unless the course of the disease is interrupted.

Q **What are routine patient costs associated with clinical trials?**

A ACA describes routine patient costs in clinical trials that health insurers must cover as "all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial." This includes items such as hospital visits, imaging or laboratory tests, and medications.

Q **What is not included in the clinical trials provision?**

A According to ACA, the clinical trial provision does not include:

- The investigational treatment, device, or service itself, which is typically covered by the trial's sponsor, such as the National Cancer Institute or a pharmaceutical company.
- Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient.
- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

Summary

The clinical trials provision of ACA goes into effect for plan years beginning on or after Jan. 1, 2014. It requires that if a "qualified individual" is in an "approved clinical trial" then the insurance plan may not:

1. Deny the individual participation in the clinical trial.
2. Deny the coverage of **routine patient costs** for items and services furnished in connection with the trial.
3. Discriminate against the individual on the basis of the individual's participation in such trial.

This only applies to non-grandfathered health insurance plans.

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Q What is the expected cost impact resulting from the implementation of the clinical trials provision of ACA?

A The expected financial impact and cost implications estimated for clinical trials are minimal since many of the routine costs referred to in the law are services that are generally covered today.

Q What is Blue Cross and Blue Shield of Illinois' (BCBSIL) Medical Policy in regards to clinical trials for 2014?

A BCBSIL has developed policies to address the mandated coverage of clinical trials. Click **here** for our recently updated medical policy regarding clinical trials.

Q Is additional federal guidance expected?

A According to an FAQ released by the federal government, we do not anticipate additional guidance regarding clinical trials in the near future. While we await guidance, we will continue to operate using a good faith interpretation of the law, and we will release more information as it becomes available.

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