



## *Cancer Clinical Trials*

---

Self-funded employers are encouraged to cover *routine costs of care* when patients are enrolled in an *approved clinical trial* (see definitions, below). Many employers cover approved clinical trials for life-threatening conditions by including appropriate language in their Summary Plan Description (SPD). When the Plan document allows, patients who participate in a clinical trial will have coverage for routine costs of care just as they do for services that take place outside a clinical trial. Several published reports indicate that the costs of treatment in a clinical trial are, at most, only slightly higher than treatment that is not part of a clinical trial. *Estimated impact for an employer to cover routine costs of care for cancer-related clinical trials is less than \$1 per member per year.*

The purpose of clinical trials in cancer is to study promising new treatments and determine whether a new treatment is safe and effective and is better (i.e., results in improved survival or cure and/or fewer side effects) than the treatment currently in use. Coverage for clinical trials is especially important when patients are being treated at large academic cancer centers. Since clinical research is a central aspect of the mission of academic cancer centers, they offer many high quality clinical trials. For some individuals, treatment available in a clinical trial is the best option, and sometimes the only option. Nationwide, average clinical trial participation rate for adults is very low (about 3%). Pediatric cancer care is more often provided as part of a clinical trial, and clinical trial participation by children with cancer is estimated at more than 50%.

By including "life-threatening illness" language in the SPD, employers can ensure that Plan participants will have coverage for routine costs of care when participating in a clinical trial.

### **Costs of Care in Clinical Trials**

"Routine" patient care costs for Clinical Trials include:

1. Covered Health Services for which Benefits are typically provided absent a Clinical Trial;
2. Covered Health Services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
3. Covered Health Services needed for reasonable and necessary care arising from the provision of an investigational item or service.

Routine costs for Clinical Trials *do not include*:

1. The experimental or investigational service or item;
2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and
3. Items and services provided by the research sponsors free of charge for any person enrolled in the trial.

The following definition may be included in the employer's SPD

**An Approved Clinical Trial is a clinical trial that is funded, conducted, or supported by centers or cooperative groups that are funded by any of the following:**

1. National Institutes of Health (NIH), including the National Cancer Institute (NCI)
2. Department of Defense (DOD)
3. Department of Veterans Affairs (VA)
4. Agency for Healthcare Research and Quality (AHRQ)
5. Centers for Medicare & Medicaid Services (CMS)
6. Centers for Disease Control and Prevention (CDC)

**An Approved Clinical Trial must also meet the following requirements:**

1. The subject or purpose of the trial must include the evaluation of an item or service that falls within a covered benefit category.
2. The trial must include therapeutic intent among its objectives. Some clinical trials study prevention and diagnosis.
3. The trial must enroll patients with diagnosed disease rather than healthy volunteers.

(Adapted from HHS, CMS)

### **Information on Clinical Trials from the National Cancer Institute**

The information below addresses key points about clinical trials. It has been adapted from the National Cancer Institute website: <http://www.nci.nih.gov/clinicaltrials/learning>

### **Ten Things to Know About Cancer Clinical Trials**

1. **Clinical trials** are research studies that involve people. Each study tries to answer scientific questions and to find better ways to prevent, diagnose or treat cancer. See [What Is a Clinical Trial?](#) as well as [Taking Part in Cancer Treatment Research Studies](#).
2. In **cancer research** a clinical trial is designed to show how a particular anticancer strategy -- for instance, a promising drug, a gene therapy treatment, a new diagnostic test, or a possible way to prevent cancer -- affects the people who receive it. A clinical trial may also compare two standard treatment options to determine which one is better. Many clinical trials, however, compare a promising *new* therapy to an available treatment that represents the standard of

care. Providers cannot charge for any drug that has not yet received FDA approval. (See definition of routine costs, below.)

3. A clinical trial is one of **the stages of a long and careful cancer research process**. Getting promising results from testing a new drug on mice, for example, is a preliminary step to human research studies. Treatments that work well in mice do not always work well in people. See [How Is a Clinical Trial Planned and Carried Out?](#)
4. People can **benefit** from clinical trials. In treatment trials, for example, participants receive high-quality cancer care -- and will be among the first to benefit if a new approach is proven to work. See [Should I Take Part in a Clinical Trial?](#)
5. **Who's eligible** to participate in a clinical trial? Each study has its own guidelines for who can participate. Generally, participants are alike in key ways - such as the type and stage of cancer, age, gender, and other factors. See [How Do I Take Part in a Clinical Trial?](#)
6. Are there **drawbacks**? New treatments under study are not always better than, or even as good as, standard care. And they may have unexpected side effects. Through a process called **informed consent** potential clinical trial participants will learn about a study's treatments and tests, and their possible benefits and risks, before deciding whether or not to participate. See [A Guide to Understanding Informed Consent](#).
7. Do some people receive a **placebo** in clinical trials? Placebos are very rarely used in treatment trials involving people who have cancer, i.e., if the current standard of care is no treatment.
8. Many treatment trials are designed to **compare a new treatment with a standard treatment**, which is the best treatment currently known for a cancer, based on results of past research. In these studies patients are randomly assigned to one group or another.
9. **Where** do clinical trials take place? They are underway all over the country - in cancer centers, other major medical centers, community hospitals and clinics, physicians' offices and veterans' and military hospitals in numerous cities and towns around the United States.
10. **Who pays for the patient care costs on clinical trials?** Health plans and managed care providers do not always cover all patient care costs in a study. What they cover varies by plan and by study. Research costs are covered by the study sponsor. See [Clinical Trials and Insurance Coverage: A Resource Guide](#).