



# CLINICAL TRIALS

## Do clinical trials have to be covered?

Yes. The legislation requires coverage of routine patient care costs related to clinical trials beginning January 1, 2014. Although the requirement does not apply to grandfathered plans, Cigna is adopting it as standard policy for all insured and self-insured plans.

It is expected that the financial will be relatively low as many of the expenses associated with clinical trials are already covered.

### **Overview**

For plan years beginning on or after January 1, 2014, routine patient care costs related to clinical trials are required to be covered by insurers for individual policies and non-grandfathered group health plans insured and self-insured.

### **Coverage for clinical trials**

An approved clinical trial is defined as a phase I, phase II, phase III or phase IV clinical trial conducted in relation to the prevention, detection or treatment of cancer or another life-threatening disease or condition.

An individual may qualify to participate in a clinical trial based on a referral from a health care professional participating in the trial, or by providing medical and scientific information establishing that participation would be appropriate.

Routine patient care services generally include items and services that typically would be covered under the plan for an individual not enrolled in a clinical trial, such as radiological services, laboratory services, intravenous therapy, anesthesia services, hospital services, physician services, office visits, room and board and medical supplies.

Plans do not have to pay for:

- The actual clinical trial or the investigational item, service or device itself
- Items and services that are provided solely for data collection and analysis 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

Routine patient services which are part of an approved clinical trial will be managed as they normally are outside a clinical trial. For example, we will pre-certify services routinely subject to precertification such as inpatient services, select outpatient services, transplant related services and services for customers in case management.