

CLINICAL TRIALS FACT SHEET



INFORMED ON REFORM

This Fact Sheet summarizes the clinical trial provision of the Patient Protection and Affordable Care Act. The Department of Health and Human Services has indicated it will not issue formal guidance on clinical trials.

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 Cigna for individual policies and non-grandfathered group health plans insured and administered by Cigna.

Cigna is adopting the expanded coverage of clinical trials as standard policy for all insured and self-insured plans.

- › Routine costs associated with clinical trials through phase III for cancer are currently covered under most Cigna plans.
- › Effective with 2014 plan years, the coverage will be expanded beyond cancer to include all conditions meeting the criteria specified in the law as well as phase IV clinical trials.

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 precertify services routinely subject to precertification such as inpatient services, select outpatient services, transplant-related services and services for customers in case management.

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