



## Clinical Trials

Effective for plan years beginning on or after Jan. 1, 2014, the Affordable Care Act (ACA) requires all non-grandfathered group health plans to provide coverage for routine patient costs incurred by a qualifying individual participating in an “approved clinical trial.” The requirement does not apply to grandfathered plans.

The clinical trials provision is effective for new and renewing health plans on or after Jan. 1, 2014. These include fully insured individual and group plans as well as self-funded plans and the Federal Employees Health Benefits Program (FEHBP) plans.

### What is an approved clinical trial?

An “approved clinical trial” is one that is conducted in relation to the prevention, diagnosis or treatment of cancer or other life-threatening diseases or conditions. A life-threatening condition is defined as any disease from which the likelihood of death is probable unless the course of the disease is interrupted. This definition is more expansive than the definition found currently in many UnitedHealthcare Certificates of Coverage (COC) and Summary Plan Descriptions.

In addition, the trial for which routine patient costs must be covered must be approved or sponsored by one of a number of federal agencies, including the National Institutes of Health, the Centers for Medicare and Medicaid Services and the Food and Drug Administration. This list is not all-inclusive.

A member is considered a qualifying individual if: (1) the member is eligible to participate in the trial according to its protocol; and (2) either a participating provider who has referred the individual to the trial concludes that participation would be appropriate, or the individual provides medical and scientific information that establishes that the individual’s participation is appropriate and consistent with the trial protocol.

### Routine patient costs explained

The requirement mandates coverage of all “routine patient costs” associated with the individual’s participation in a clinical trial. This means all medically necessary health care provided to the individual for purposes of the trial, consistent with a plan’s medical coverage, and services that would be covered for those not enrolled in clinical trials.

Such services include those rendered by a physician, diagnostic or laboratory tests, and other services provided during the course of treatment for a condition or one of its complications that are consistent with the usual and customary standard of care.



Routine patient costs do not include the actual device, equipment or drug that is being studied. Also excluded are: items and services that are provided solely to satisfy data collection and analysis needs that are not used in direct clinical management of the patient; or a service that is clearly inconsistent with the widely accepted and established standards of care for a particular disease or condition.

The ACA provides that coverage may be subject to the limitations and requirements set forth in a member's benefit plan documents. For example, plans are not required to provide benefits for routine patient care services provided outside of the plan's network area unless out-of-network benefits are otherwise provided under the plan.

Based upon language set forth in UnitedHealthcare's standard COC, UnitedHealthcare already covers routine patient costs associated with a Phase I, II or III clinical trial for the treatment of cancer, cardiovascular disease (cardiac/stroke) and surgical musculoskeletal disorders of the spine, hips and knees.

## **How clinical trial coverage is changing**

The clinical trial mandate under the ACA expands in part the coverage provided under UnitedHealthcare's standard COC in the following manner:

- Coverage will be expanded to include routine patient costs associated with preventive and diagnostic clinical trials in addition to therapeutic clinical trials.
- Coverage will be expanded to include routine patient costs related to clinical trials covering "other life threatening conditions" in addition to cancer, cardiovascular and surgical musculoskeletal disorders of the spine, hips and knees.
- Coverage will be expanded to include routine patient costs associated with a Phase IV trial in addition to the routine patient costs associated with Phase I, II and III trials. Phase IV trials take place after the drug or other intervention has been marketed, and are designed to monitor its effectiveness in the general population as well as any adverse effects. Subject to FDA approval, they may be ongoing for variable periods of time.

In addition to providing coverage for routine patient costs relating to cancer, cardiovascular or musculoskeletal diseases, self-funded customers may elect to provide coverage without diagnostic restriction. A plan may choose to offer greater coverage than ACA requires, including coverage for costs associated with trials relating to different conditions and conducted for different purposes.

Generally, experimental, investigational and unproven services are excluded unless the patient's condition is life-threatening, as defined in the enrollee's benefit document or greater coverage is required by state mandate. UnitedHealthcare complies with state mandates that provide for greater coverage than ACA.

## **UnitedHealthcare's approach**

UnitedHealthcare has updated its Certificate of Coverage and Summary Plan Description templates to ensure full alignment with ACA requirements. The COCs for those states requiring greater coverage are updated accordingly.

At this time it is anticipated that the additional plan cost for clinical trials coverage will be minimal.

Anticipated costs are solely estimates and not guarantees of future performance or experience. Actual costs may vary based on a variety of factors, including, but not limited to, plan design, claims experience, utilization and population demographics.

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