

5 Basic Things to Know About Clinical Trials

1. Effective for plan years beginning on or after Jan. 1, 2014, all non-grandfathered group health plans must provide coverage for “routine patient costs” incurred by members with cancer and other life-threatening diseases who qualify to participate in an “approved clinical trial.”
2. “Routine patient costs” are all medically necessary health care services provided for the purposes of the trial, including those provided by doctors, diagnostic or laboratory tests and other services that are consistent with the customary standard of patient care, and would be otherwise covered under the medical plan if the member was not a trial participant.
3. Routine patient costs do **not** include the actual device, equipment or drug that is being studied as part of the clinical trial. Also excluded are items or services not used in the direct clinical management of the patient, such as those solely to satisfy data collection and analysis needs, or items and services clearly inconsistent with accepted standards of care for the particular diagnosis.
4. Members may qualify for clinical trials if they meet the protocols of the trial and a participating provider deems them eligible and refers them to the trial as appropriate for the purpose of the trial, consistent with the member’s benefit plan documents. Members also can provide medical and scientific information to establish that their participation in the trial is appropriate.
5. The Affordable Care Act (ACA) clinical trials mandate expands existing clinical trial coverage to now include preventive trials and Phase IV trials that involve monitoring the effectiveness of the device or drug that is part of the clinical trial. The additional plan costs for clinical trials coverage are estimated to be minimal, but can vary based on plan design, claims experience, utilization and population demographics.

The content provided is for informational purposes only and does not constitute medical advice. Insurance coverage provided by or through UnitedHealthcare Insurance Company or its affiliates. Administrative services provided by United HealthCare Services, Inc., or its affiliates.

This communication is not intended, nor should it be construed, as legal or tax advice. Please contact a competent legal or tax professional for legal advice, tax treatment and restrictions. Federal and state laws and regulations are subject to change.

6/13

