Coverage for Members in Clinical Trials – December 2013

Beginning on January 1, 2014, the Affordable Care Act (ACA) requires certain benefit coverage for members taking part in approved clinical trials. Members participating in clinical trials are likely to need more blood work, scans, tests, and experience side effects that need treatment, and this portion of the law was created to help address these needs. The new law requires coverage for “routine health care” for members of non-grandfathered health plans, when these members take part in an approved clinical trial. The clinical trial itself is not required to be covered under the law. These benefits are effective upon renewal of the non-grandfathered health plan on or after January 1, 2014.

Please note that not all health plans are subject to requirements under the ACA, and plans under the new requirements have varied effective dates. Providers should continue to verify eligibility and benefits for all members.

The following frequently asked questions provide additional detail about coverage for members in clinical trials.

Q. What is an approved clinical trial?
A. An approved clinical trial is any of the four phases that studies the prevention, detection, or treatment of cancer or other life-threatening conditions. The trial has to be federally funded, funded by a government agency, or a non-government agency that is recognized by the National Institutes of Health.

Q. What does “routine care” for a person in a clinical trial mean?
A. “Routine care” or “routine patient care” in a clinical trial means the range of medical services people with a certain diagnosis might need, including other doctor visits, hospital stays, tests, and care related to the illness or disease. It also includes treatment for side effects and other medical issues that might come up as a result of the trial.

Q. Can members who need “routine care” during a clinical trial use a doctor suggested by or partnering with the doctor of a clinic running the trial, even if the provider is not in network?
A. Out-of-network services will be covered at the out-of-network benefit level. In-network benefits will be covered at the in-network benefit level. In certain situations, Connecticut state law (38a-504d & 38a-542d) mandates that treatment at an out-of-network hospital as provided in subdivision (1) of subsection (a) of this section shall be made available by the out-of-network hospital and the insurer or health care center at no greater cost to the insured person than if such treatment was available in-network.

Q. Are drug trials covered?
A. We do not cover the investigational drug. This exclusion is allowed by the law. Studies or investigations done as part of an investigational new drug application that have been reviewed by the Food and Drug Administration (FDA) are covered, as are studies and investigations done for drug trials which are exempt from the investigational new drug application.

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Q. What won’t be covered for a member participating in a clinical trial?
A. Under the law, we do not have to cover the following benefits or services:
   - The investigational item, device, or service itself
   - Items and services that are only given to satisfy data collection and analysis needs but are not used in the direct clinical management of the member
   - A service that is not in line with widely accepted and established standards of care for a particular diagnosis
   - Any item or service that is paid for, or should have been paid for by the sponsor of the trial.

Q. When will contract language be updated for clinical trials?
A. Contract language has been filed and approved with the appropriate Departments of Insurance (DOIs). Contracts for individuals and groups, new and renewing on and after 1/1/2014 will reflect the appropriate clinical trials language.