Routine Care Provided to Enrollees Participating in Clinical Trials

The MCO shall cover any item or service provided to an enrollee participating in a qualifying clinical trial to the extent that the item or service would otherwise be covered for the enrollee when not participating in the qualifying clinical trial. This includes any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation.

Qualifying Clinical Trial

A qualifying clinical trial is defined as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition that meets any of the following criteria:

- The study or investigation is approved, conducted, or supported (which may include funding) by one or more of the following:
  - The National Institutes of Health.
  - The Centers for Disease Control and Prevention.
  - The Agency for Healthcare Research and Quality.
  - The Centers for Medicare & Medicaid Services.
  - A cooperative group or center of any of the entities described in subclauses (I) through (IV) or the Department of Defense or the Department of Veterans Affairs.
  - A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
  - The study or investigation is approved or funded by one or more of the following and has been reviewed and approved through a system of peer review comparable to the system of peer review of studies and investigations used by the National Institutes of Health which assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
    - The Department of Veterans Affairs
    - The Department of Defense.
    - The Department of Energy.
- The clinical trial is conducted pursuant to an investigational new drug exemption under section 335(i) of Title 21 or an exemption for a biological product undergoing investigation under section 262(a)(3) of this title.
- The clinical trial is a drug trial that is exempt from having such an investigational new drug application.

Coverage determinations shall be:

- Expedited and completed within 72 hours;
- Made without limitation on the geographic location or network affiliation of the health care provider treating such individual or the principal investigator of the qualifying clinical trial;

- Based on attestation regarding the appropriateness of the qualifying clinical trial by the health care provider and principal investigator using the following form and kept on file by the provider: https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx; and
- Completed without any requirement of submission of the protocols of the qualifying clinical trial, or any other documentation that may be proprietary or determined by the HHS Secretary to be burdensome to provide.

Coverage Limitations

The MCO shall not cover any of the following:

- The investigational item or service that is the subject of the qualifying clinical trial;
- Any service provided to the individual solely to satisfy data collection and analysis needs for the qualifying clinical trial and is not used in the direct clinical management of the individual; and
- Services not otherwise covered by the MCO.