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Routine Care Provided to Beneficiaries ~~Enrolled~~ Participating in Clinical Trials

~~Clinical trials are defined as biomedical or behavioral research studies on human participants and are designed to answer specific questions about biomedical or behavioral interventions. These studies include new treatments and known interventions that warrant further study and comparison.~~

~~Louisiana Medicaid reimburses for the routine, non-experimental/investigational services furnished as a result of a beneficiary participating in a clinical trial when the services:~~

- ~~• Would otherwise be provided to a beneficiary who is not participating in a clinical trial;~~
- ~~• Are not unique to the experimental or investigational treatment; and~~
- ~~• Are not covered by the clinical trial sponsor.~~

~~All services are covered under the same policies that would apply if the beneficiary were not a participant in a clinical trial.~~

~~Louisiana Medicaid covers any item or service provided to a beneficiary participating in a qualifying clinical trial to the extent that the item or service would otherwise be covered for the beneficiary 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:~~

- ~~1. The study or investigation is approved, conducted, or supported (which may include funding) by one or more of the following:~~
 - ~~a. The National Institutes of Health;~~
 - ~~b. The Centers for Disease Control and Prevention;~~
 - ~~c. The Agency for Healthcare Research and Quality;~~
 - ~~d. The Centers for Medicare & Medicaid Services;~~

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- e. A cooperative group or center of any of the entities described in 1.a-1.d above or the Department of Defense or the Department of Veterans Affairs;
 - f. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or
 - g. 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 that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
 - i. The Department of Veterans Affairs;
 - ii. The Department of Defense; and/or
 - iii. The Department of Energy.
2. The clinical trial is conducted pursuant to an investigational new drug exemption under Section 355(i) of Title 21 [21 U.S.C. 355(i)] or an exemption for a biological product undergoing investigation under Section 262(a)(3) of Title 42 [42 U.S.C. 262(a)(3)]; and
3. The clinical trial is a drug trial that is exempt from having such an investigational new drug application.

Coverage determinations shall be:

- 1. Expedited and completed within 72 hours;
- 2. 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;
- 3. 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.medicare.gov/resources-for-states/downloads/medicaid-attest-form.docx>; and

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4. 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

Louisiana Medicaid does not cover any of the following:

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