Utah Department of Health & Human Services

Qualifying Clinical Trials and Medicaid

Effective January 1, 2022, the Medicaid State Plan was updated to align with amendments made to Section 1905(a) of the Social Security Act. The State Plan change dictates that Medicaid reimburse costs associated with participation in qualifying clinical trials for Medicaid members.

Note: that the Consolidated Appropriations Act does NOT require Medicaid to cover the investigational treatments associated with a qualifying clinical trial but does require states to cover routine patient care costs of items and services furnished to the Medicaid member as part of their participation in the qualifying clinical trial.

The following is a list of frequently asked questions (FAQs) regarding Medicaid's coverage of qualifying clinical trials.

What is a qualifying clinical trial?
A qualifying clinical trial, as defined by Consolidated Appropriations Act, 2021, is 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. Additionally, a qualifying clinical trial must be authorized by a governing agency outlined in the Consolidated Appropriations Act, 2021.

What is a serious or life-threatening disease or condition?
Serious and life-threatening are defined in the Affordable Care Act. In summary:

- The term "serious" refers to a disease or condition:
  - Involving extreme physical pain
  - Involving a substantial risk of death
  - Involving protracted loss or impairment of the function of a bodily member, organ, or mental faculty; or
  - Requiring medical intervention such as surgery, hospitalization, or physical rehabilitation.
- A "life-threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

What law requires Medicaid to cover routine patient care costs of items and services related to participation in a qualifying clinical trial?
Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260) (section 210) amended section 1905(a) of the Social Security Act makes coverage of any routine patient costs associated with a member participating in a qualifying clinical trial a mandatory benefit under the Utah Medicaid State Plan. However, the clinical trial itself is not a covered benefit under this amendment.

What type of clinical trial qualifies for coverage by Medicaid?
Providers and the principal investigator (entity conducting the qualifying clinical trial) must validate the appropriateness of the trial by using the National Clinical Trial Number found at https://clinicaltrials.gov/. The National Clinical Trial Number must be placed on the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial Form.

What is covered by Medicaid for members participating in a qualifying clinical trial?
Routine patient care costs of items and services furnished to the Medicaid member as part of their participation in the qualifying clinical trial are covered. Examples of routine costs in a clinical trial include:

- Physician services
- Laboratory services
- Equipment and Supplies
- Imaging
- Any other medically-necessary services that assist with preventing, diagnosing, monitoring, or treating complications arising from clinical trial participation

What is NOT covered by Medicaid for a Medicaid member participating in a qualifying clinical trial?
Any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial, **is not covered**.

Routine patient cost **does not** include any item or service that is provided to the member solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the member.

Are routine patient costs of items and services related to qualifying clinical trials covered by fee-for-service Medicaid or managed care plans?
Coverage is provided based on the member's enrollment status. If the member is enrolled with a managed care plan, the plan is responsible for covering the approved services. If the member is enrolled with fee-for-service, fee-for-service is responsible for covering the approved services related to participation in the qualifying clinical trial.

What are the coverage requirements, and when is a prior authorization required for a qualifying clinical trial?
Not all services that are a part of the clinical trial require a prior authorization. However, when they do, providers must include the completed Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial Form along with the completed Prior Authorization form. Providers can validate if a service requires a prior authorization through the Coverage and Reimbursement Code Lookup. Whether or not the service requires a prior authorization, providers should keep the attestation form on file in the member's medical record.

If the member is enrolled with fee-for-service, include this Prior Authorization Request Form. Fax both forms to 801-536-0162 or email both forms to fax_allotherauth_prior@utah.gov. If the member is enrolled in a managed care plan, contact that plan to fill out the appropriate prior authorization form.

Example of complete process

1. A Medicaid member sees their Health Care Provider (HCP) and is found to be an appropriate candidate for a treatment option that is currently involved in a clinical trial.
2. The Prinicipal Investigator (PI) and HCP complete the Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial Form by filling out the following fields:
    a. Participant [member] name;
    b. Medicaid ID;

c. National Clinical Trial Number (this number is found on clincialtrials.gov);
d. PI name;
e. PI attestation to the appropriateness of the qualified clinical trial;
f. PI signature;
g. HCP (if different than the PI) name;
h. HCP (if different than the PI) attestation to the appropriateness of the qualified clinical trial; and
i. HCP (if different than the PI) signature.

3. The HCP sends the completed Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial Form to Medicaid. If the member is not enrolled in a managed care plan (aka Fee-For-Service), include the completed Prior Authorization Request Form and send by fax to 801-536-0162 or by email to fax_allotherauth_prior@utah.gov. If the member is enrolled in a managed care plan, the HCP works with the managed care plan to submit the appropriate prior authorization form.
4. The PI and HCP keep copies of the completed forms for their records.
5. The Prior Authorization decision is communicated to the HCP within 72 hours of the submission.
6. If the PA is approved, the HCP submits the claim to Medicaid for reimbursement.