Clinical Trials Policy

Page updated: February 2023

Pursuant to *Section 1396d(gg)(2) of Title 42 of the United States Code*, Medi-Cal covers routine patient care costs for beneficiaries participating in a qualifying clinical trial.

Definitions

Routine patient care costs are defined as any item or service provided to the individual under the qualifying clinical trial, including:

- Any item or service provided to prevent, diagnose, monitor, or treat complications resulting from such participation
- Any item or service that would be provided by the Medi-Cal program outside of participation in a qualifying clinical trial
- Any item or service required for the provision of the investigational item or service, including the administration of the investigational item or service

The following services are excluded from routine patient care costs and are not Medi-Cal reimbursable:

- Investigational item or service that is the subject of the qualifying clinical trial
- Any item or service associated with the qualifying clinical trial that are excluded from coverage by the Medi-Cal program
- Services not directly associated with health care, such as travel, housing, companion expenses, and other non-clinical expenses associated with the clinical trial that are not otherwise covered by Medi-Cal
- Any item or service provided solely for data collection and analysis for the qualifying clinical trial

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. Approved clinical trials are available at the Clinical Trials Database for the United States.

Coverage Determination

- Must be regardless of geographic location or network affiliation of the treating Medi-Cal provider or principal investigator of the qualifying clinical trial
- Must be based on the approval by the Medi-Cal provider and principal investigator regarding the beneficiary's appropriateness for the qualifying clinical trial
- Medi-Cal providers are required to include the clinical trial registry number on the electronic claim equivalent by submission of the Medicaid Attestation form. The attestation form must also be signed by the Principal Investigator.

TAR Requirements

Services requiring authorization may be approved for a patient diagnosed with and accepted into a clinical trial when the criteria listed above are met.

MEDICAID ATTESTATION FORM ON THE APPROPRIATENESS OF THE QUALIFIED CLINICAL TRIAL

Participant

Participant Name: _____

Medicaid I.D.: _____

Qualified Clinical Trial

National Clinical Trial Number (from clinicaltrials.gov): _____

Principal Investigator Attestation

Principal Investigator Name: _____

☐ I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

☐ The Principal Investigator is also the Health Care Provider and hereby attests to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: _____ Date: _____
(*signature of principal investigator*) (*month, day, year*)

Health Care Provider Attestation

Health Care Provider Name: _____

☐ I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.

Signature: _____ Date: _____
(*signature of health care provider*) (*month, day, year*)

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-0193. Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Figure 1: Medicaid Attestation Sample Form

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.