APPROPRIATENESS OF THE QUALIFYING CLINICAL TRIAL

Section 210 of the Consolidated Appropriations Act of 2021 amended section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30): coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials. In addition, section 1902(a)(10)(A) of the Act was amended to add coverage of services and costs provided in connection with qualified clinical trials to the list of required services. Section 1937(b)(5) of the Act was also amended to make it mandatory for benchmark benefit plans and benchmark equivalent plans, also known as Alternative Benefit Plans, to cover routine patient services and costs furnished in connection with Medicaid beneficiaries who are participating in qualifying clinical trials.

A "qualifying clinical trial" 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 as described in section 1905(a)(30)(i) of the Act, and the study or investigation is approved, conducted or supported by one or more of the following:

- The National Institutes of Health (NIH);
- The Centers for Disease Control and Prevention (CDC);
- The Agency for Health Care Research and Quality (AHRQ);
- The Centers for Medicare & Medicaid Services (CMS);
- A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs;
- A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants; or
- If comparable to the system of peer review studies and investigations used by the National Institute of Health, and assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
    - The Department of Energy
    - The Department of Veterans Affairs
    - The Department of Defense

Also considered qualified is a clinical trial conducted on an investigational new drug that is exempted under section 505(i) of the Federal Food, Drug, and Cosmetic Act, a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act, or a drug trial that is exempt from being required to have an exemption in section 505(i) of the Federal Food, Drug and Cosmetic Act or section 351(a)(3) of the Public Health Service Act.

Information regarding qualifying clinical trials is publicly available on a website maintained by the Secretary, at clinicaltrials.gov and/or can be accessed at (*principle investigator provides link*).

In order for a Medicaid beneficiary to receive coverage of routine patient services and costs furnished in connection with participation in qualifying clinical trials, the principle investigator of the clinical trial and the participant's health care provider must attest that the clinical trial

meets the requirements of a federally sponsored clinical trial and is appropriate for the Medicaid beneficiary.

- **PRINCIPLE INVESTIGATOR ATTESTATION**

I, _____ principle investigator of the qualifying clinical trial _____
(*name/subject of qualified clinical trial*),
do hereby attest to the appropriateness of the clinical trial in which

_____ _____
(name of Medicaid beneficiary) (*participant Medicaid I.D.*)
is participating, and that the clinical trial meets the requirements of a federally sponsored clinical trial. This qualifying clinical trial may be accessed at_____
(*link to the qualified clinical trial*)

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

Physician NPI**:** _____
(*if applicable***)**

- **HEALTH CARE PROVIDER ATTESTATION**

I, _____ health care provider for the clinical trial participant, _____ _____
(*name of participant*), (*participant Medicaid I.D.)*
do hereby attest that it is appropriate for _____
(*name of participant*),
a Medicaid beneficiary, to participate in the above named qualified clinical trial and that in accordance with section 1905(a)(30) of the Act, the beneficiary is entitled to receive coverage of routine patient services and costs furnished in connection with participation in a qualifying clinical trial.

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

Physician NPI**:** _____

Information regarding this qualifying clinical trial that is publicly available on a website maintained by the Secretary of the Department of Health and Human Services may optionally be provided as an attachment to this form; however, coverage determinations shall not require submission of the protocols of the qualifying clinical trial or any other documentation that may be proprietary or determined by the Secretary to be burdensome.