Connecticut Department of Social Services
Medical Assistance Program **Provider Bulletin 2024-31**
www.ctdssmap.com **May 2024**

TO: Physicians, Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), and Hospitals
RE: Attestation Form for Qualifying Clinical Trials

In December 2021, the Centers for Medicare and Medicaid Services (CMS) issued the UPDATED: Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials guidance, requiring state Medicaid program coverage of routine costs associated with qualifying clinical trials in which members are enrolled. The Connecticut Medical Assistance Program (CMAP) has covered and will continue to cover these costs and is updating policy in compliance with CMS requirements by posting the Medicaid Attestation Form for Qualifying Trials.

"Qualifying Clinical Trial" is defined in the referenced guidance above. "Routine costs" do not include any investigational item or service that is the subject of the qualifying clinical trial and is not otherwise covered outside of the clinical trial under the state plan, waiver, or demonstration project.

Effective immediately, the Medicaid Attestation Form for Qualifying Clinical Trials will be available on CMAP Website: www.ctdssmap.com listed under "Authorization/Certification Forms" in the "Forms" section of the web page.

All completed clinical trial attestation forms must be kept in the HUSKY Health member's medical record and retained for at least five years or longer in accordance with statute or regulation.

The attestation form must be completed prior to starting the trial and made available upon request to the Department of Social Services (DSS) or DSS's medical Administrative Services Organization (ASO) CHNCT. Providers are not required to submit this form with the claim, nor should they transmit a copy of this form to DSS, unless otherwise instructed to do so.

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 notconduct or sponsor, and a person is not required to respond to, a collection of information unlessit 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.