Ohio | Department of Medicaid

Mike DeWine, Governor
Jon Husted, Lt. Governor

Maureen M. Corcoran, Director

Medicaid Advisory Letter (MAL) No. 666

DATE: December 9, 2022

TO: Eligible Providers of Medicaid Services
CC: Chief Executive Officers, Managed Care Entities (MCEs)

FROM: Maureen M. Corcoran, Director

SUBJECT: Services Related to Qualified Clinical Trials and CMS Required Attestation Form

Summary

This guidance applies to items and services furnished to Medicaid recipients, including recipients enrolled in the Alternative Benefit Plan (ABP), who are participating in qualified clinical trials on or after January 1, 2022.

The Center for Medicare and Medicaid Services (CMS) issued State Medicaid Director Letter #21-005 mandating Medicaid coverage, effective January 1, 2022, for routine patient costs associated with participation in qualified clinical trials. CMS requires this coverage be based on a written attestation, to be completed by the healthcare provider treating the beneficiary or the principal investigator of the qualified clinical trial, regarding the appropriateness of the qualified clinical trial. CMS developed a streamlined form for state use as of July 1, 2022, titled "Medicaid Attestation Form on the Appropriateness of the Qualified Clinical Trial" to capture this attestation. The form is included with this notice but may also be found on the "New & Notable Resource Center" page on the Medicaid.gov website.

The Ohio Department of Medicaid (ODM) made necessary updates to Ohio Administrative Code (OAC) rule 5160-1-61, the Ohio Medicaid state plan, and the ABP to comply with these changes. ODM, including the Managed Care Entities (MCEs), will not be issuing a separate attestation form; therefore, providers are expected to use the streamlined form developed by CMS. **This CMS form must be collected and kept on file for Medicaid recipients participating in a qualified clinical trial as of July 1, 2022.** For Medicaid recipients who participated in a qualified clinical trial between January 1, 2022 and June 30, 2022, providers may choose to use the form developed by CMS or another form of attestation that captures the same information.

If the Medicaid recipient is participating in more than one clinical trial, an attestation form is required for each qualified trial. Unless specifically requested, there is no need for providers to submit the form to ODM or the MCEs when submitting claims for services related to clinical trials.

Access to Rules and Related Material

The main Ohio Department of Medicaid (ODM) web page includes links to valuable information about its services, programs, and rules; the address is http://www.medicaid.ohio.gov

Additional Information

Questions pertaining to this letter should be addressed to:

Ohio Department of Medicaid
Bureau of Health Plan Policy
P.O. Box 1461
Columbus, OH 43216-1461
Telephone (800) 686-1516

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.