MEDICAID POLICY INFORMATION SHEET

Policy Analyst: Lisa DiLernia

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Initial ☐ Public Comment ☒ Final ☐

Brief description of policy:

This bulletin establishes the requirement for providers to submit the Attestation to the Appropriateness of the Qualified Clinical Trial form with: (1) claims for routine patient costs for items and services associated with a qualified clinical trial, and (2) prior authorization (PA) requests for those items and services associated with a qualified clinical trial that require PA.

Reason for policy (problem being addressed):

Section 210 of the Consolidated Appropriations Act of 2021 requires Medicaid to obtain an attestation by the principal investigator and health care provider to the appropriateness of the clinical trial before providing payment for items and services. The Centers for Medicare & Medicaid Services (CMS) recently published a form for states to utilize for this purpose.

Budget implication:

☒ budget neutral
☐ will cost MDHHS $, and (select one) budgeted in current appropriation
☐ will save MDHHS $

Is this policy change mandated per federal requirements?

Yes, Section 210 of the Consolidated Appropriations Act of 2021.

Does policy have operational implications on other parts of MDHHS?

Program Review Division, Claims Division

Does policy have operational implications on other departments?

No.

Summary of input:

☐ controversial
☒ acceptable to most/all groups
☐ limited public interest/comment

Supporting Documentation:

State Plan Amendment Required: ☐ Yes ☒ No If Yes, please provide status: ☐ Approved ☐ Pending ☐ Denied Date: Approval Date:	Public Notice Required: ☐ Yes ☒ No If yes, Submission Date:

DRAFT FOR PUBLIC COMMENT Michigan Department of Health and Human Services		
	Project Number: 2245-Practitioner	**Date:** October 18, 2022

Comments Due: November 22, 2022
Proposed Effective Date: January 1, 2023
Direct Comments To: Lisa DiLernia
Address:
E-Mail Address: dilernial@michigan.gov
Phone: 517-284-1203 **Fax:**

Policy Subject: Updates to the Coverage of Routine Patient Costs for Items and Services Associated with Participation in a Qualifying Clinical Trial

Affected Programs: Medicaid, Healthy Michigan Plan, Children's Special Health Care

Distribution: All Providers

Summary: In accordance with Section 210 of the Consolidated Appropriations Act of 2021, this bulletin establishes the requirement for providers to submit the Attestation to the Appropriateness of the Qualified Clinical Trial form with: (1) claims for routine patient costs for items and services associated with a qualified clinical trial, and (2) requests for prior authorization (PA) for those items and services associated with a qualified clinical trial that require PA.

Purpose: The purpose of the bulletin is to provide practitioners with additional guidance and the template developed by the Centers for Medicare & Medicaid Services to meet the attestation requirements within the Act.

Cost Implications: Budget neutral.

Potential Hearings & Appeal Issues: None anticipated.

State Plan Amendment Required: Yes ☐ No ☒ **If yes, date submitted:**	**Public Notice Required: Yes ☐ No ☒** **Submitted date:**

Tribal Notification: Yes ☐ No ☒ - Date:

THIS SECTION COMPLETED BY RECEIVER

☐ **Approved**	☐ **No Comments**
	☐ **See Comments Below**
☐ **Disapproved**	☐ **See Comments in Text**

Signature:	**Phone Number**
Signature Printed:	
Bureau/Administration *(please print)*	**Date**

Proposed Policy Draft

Michigan Department of Health and Human Services
Behavioral & Physical Health and Aging Services Administration

Distribution: All Providers

Issued: December 1, 2022 (Proposed)

Subject: Updates to the Coverage of Routine Patient Costs for Items and Services Associated with Participation in a Qualifying Clinical Trial

Effective: January 1, 2023 (Proposed)

Programs Affected: Medicaid, Healthy Michigan Plan, Children's Special Health Care

The purpose of this bulletin is to provide updated information about the Medicaid program policy requirements related to coverage of routine patient costs for items and services associated with participation in a qualified clinical trial. Effective for items and services provided on and after January 1, 2023, a completed Attestation to the Appropriateness of the Qualified Clinical Trial form (BPHASA-2210) is required for coverage of routine patient costs for items and services furnished in connection with a beneficiary's participation in a qualified clinical trial. The form represents the attestation by the principal investigator and health care provider to the appropriateness of the clinical trial, as required by Section 210 of the Consolidated Appropriations Act of 2021.

The BPHASA-2210 must be completed and signed by both the principal investigator of the clinical trial and a qualified health care provider. Qualified health care providers include licensed providers that are part of the beneficiary's health care team such as, but not limited to; the beneficiary's primary care, specialty, treating, referring, or ordering provider or the principal investigator of the clinical trial. The completed BPHASA-2210 must be submitted with:

- Claims - Submit via the Community Health Automated Medicaid Process System (CHAMPS), Document Management Portal, with claims for routine patient costs furnished in connection with a qualifying clinical trial (Refer to the Billing & Reimbursement for Professionals chapter of the Michigan Department of Health and Human Services [MDHHS] Medicaid Provider Manual for additional information)
- Prior Authorization (PA) Requests - Submit via CHAMPS direct data entry with PA requests for items and services provided in connection with a qualifying clinical trial that require PA (Refer to the General Information for Providers chapter of the MDHHS Medicaid Provider Manual for additional information)

All other policy requirements for coverage of routine patient costs for items and services furnished in connection with a beneficiary's participation in a clinical trial remain unchanged.

Attestation to the Appropriateness of the Qualified Clinical Trial

Instructions for BPHASA-2210

General Information

BPHASA-2210 is a mandatory attestation form on the appropriateness of a qualified clinical trial in which a beneficiary is participating. This form is required for coverage of routine patient costs for items and services furnished in connection with the beneficiary's participation in a clinical trial.

The completed BPHASA-2210 must be submitted with:

- Claims - Submit via CHAMPS, Document Management Portal, with claims for routine patient costs furnished in connection with a qualifying clinical trial (Refer to the Billing & Reimbursement for Professionals Chapter of the MDHHS Medicaid Provider manual for additional information)
- Prior Authorization (PA) Requests - Submit via CHAMPS direct data entry with PA requests for items and services provided in connection with a qualifying clinical trial that require PA (Refer to the General Information for Providers Chapter of the MDHHS Medicaid Provider Manual for additional information)

For additional information on how to submit documentation with claims or requests for prior authorization, refer to Community Health Automated Medicaid Processing System (CHAMPS) (michigan.gov)

Completion Instructions

BPHASA-2210 must be signed by both:

- Principal investigator of the specified clinical trial, AND
- Health care provider
  - May also be the principal investigator,
  - Qualified health care providers include licensed providers that are part of the beneficiary's health care team such as, but not limited to, the beneficiary's primary care, specialty, treating, referring, or ordering provider.

Questions should be directed to Provider Support at ProviderSupport@michigan.gov

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
Insert Signature of Principal Investigator	Insert 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
Insert Signature of Health Care Provider	Insert 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.

AUTHORITY: Title XIX of the Social Security Act
COMPLETION: Is Voluntary, but is required if payment from applicable program is sought.

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