

BULLETIN

Bulletin Number: MMP 22-42

Distribution: All Providers

Issued: December 29, 2022

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

Effective: February 1, 2023

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

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.

For items and services provided on and after February 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 attestations by the principal investigator and the health care provider to the appropriateness of the clinical trial, as required by Section 210 of the Consolidated Appropriations Act of 2021.

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 who 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, pharmacist, or the principal investigator of the clinical trial. The completed BPHASA-2210 must be submitted with:

- Claims - Submit via the Community Health Automated Medicaid Processing 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.)

- Pharmacy PA Requests - to submit a Fee-for-Service pharmacy PA request, visit <https://michigan.magellanrx.com> >> Provider Portal >> Forms >> Prior Authorization Forms. For questions related to Fee for Service pharmacy PA requests, contact the Magellan Pharmacy Technical Call Center at 877-624-5204. For information related to Medicaid Health Plan pharmacy PA requests, visit www.michigan.gov/MCOPharmacy.

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.

Refer to the individual Medicaid Health Plan or Integrated Care Organization for submission processes associated with the Attestation to the Appropriateness of the Qualified Clinical Trial form (BPHASA-2210).

Manual Maintenance

Retain this bulletin until the information has been incorporated into the Michigan Medicaid Provider Manual.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Health and Human Services, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mailed to ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, NPI number, and phone number so you may be contacted if necessary. Typical Providers may phone toll-free 1-800-292-2550. Atypical Providers may phone toll-free 1-800-979-4662.

An electronic copy of this document is available at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms.

Approved

Farah Hanley
Chief Deputy Director for Health

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 Medicaid 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 \(CHAMPS\) \(michigan.gov\)](https://www.michigan.gov/CHAMPS)

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

<u>Participant</u>	
Participant Name	
Medicaid I.D.	
<u>Qualified Clinical Trial</u>	
National Clinical Trial Number (from clinicaltrials.gov)	
<u>Principal Investigator Attestation</u>	
Principal Investigator Name	
<input type="checkbox"/> I hereby attest to the appropriateness of the qualified clinical trial in which the individual identified above is participating.	
<input type="checkbox"/> 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
<u>Health Care Provider Attestation</u>	
Health Care Provider Name	
<input type="checkbox"/> 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 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 Security Boulevard, 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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