MEDICAID POLICY INFORMATION SHEET

Policy Analyst: Lisa DiLernia

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Initial ☐ Public Comment ☒ Final ☐

Brief description of policy:

This bulletin outlines program coverage of routine patient costs for items and services associated with participation in a qualifying clinical trial.

Reason for policy (problem being addressed):

The Consolidated Appropriations Act of 2021, Section 210, requires states to cover routine patient costs for items and services furnished in association with participation in a clinical trial effective January 1, 2022 and include a reference to such coverage in the state plan. In response to the SPA, this bulletin is being issued to outline program coverage of such services.

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, the Consolidated Appropriations Act of 2021.

Does policy have operational implications on other parts of MDHHS?

Yes - Claims Processing and Program Review 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: **11/30/21**

DRAFT FOR PUBLIC COMMENT Michigan Department of Health and Human Services		
	Project Number: 2154-Practitioner	**Date:** January 25, 2022

Comments Due: March 1, 2022
Proposed Effective Date: As Indicated
Direct Comments To: Lisa DiLernia
Address:
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Policy Subject: 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 Services

Distribution: All Providers

Summary: In response to the Consolidated Appropriations Act of 2021, Section 210, this bulletin outlines coverage of routine patient costs for items and services associated with participation in a qualifying clinical trial effective January 1, 2022.

Purpose: This bulletin is being issued in conjunction with a State Plan Amendment to comply with the Consolidated Appropriations Act of 2021, which requires states to include a reference in their state plan to the coverage of routine patient costs for items and services associated with participation in a qualifying clinical trial.

Cost Implications: None anticipated.

Potential Hearings & Appeal Issues: None anticipated.

State Plan Amendment Required: Yes ☒ **No** ☐ **If yes, date submitted:** Pending	**Public Notice Required: Yes** ☒ **No** ☐ **Submitted date:** November 30, 2021

Tribal Notification: Yes ☒ **No** ☐ **- Date:** November 2, 2021

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
Health and Aging Services Administration

Distribution: All Providers

Issued: April 1, 2021 (Proposed)

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

Effective: As Indicated (Proposed)

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

NOTE: Implementation of this policy is contingent upon State Plan Amendment approval from the Centers for Medicare & Medicaid Services (CMS).

This bulletin outlines Medicaid program requirements for ensuring coverage of routine patient costs associated with participation in qualifying clinical trials. This policy implements Section 210 of the Consolidated Appropriations Act of 2021 and applies to items and services furnished to Medicaid beneficiaries who are participating in a qualifying clinical trial on and after January 1, 2022.

Covered Services

The program covers routine patient costs furnished in connection with participation in a qualifying clinical trial. Routine patient costs are any item or service provided to the beneficiary under the qualifying clinical trial.

Routine patient costs are defined as any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial to the extent that the provision of such items or services to the beneficiary would otherwise be covered outside the course of participation in the qualifying clinical trial under the state plan or waiver. Routine patient costs also include any item or service required solely for the provision of the investigational item or service that is the subject of the qualifying clinical trial, including the administration of the investigational item or service. Examples of routine costs include otherwise covered physician services or laboratory or medical imaging services that assist with prevention, diagnosis, monitoring or treatment of complications arising from clinical trial participation.

Noncovered Services

Services considered experimental or investigational are not a covered benefit. This includes the experimental or investigational drug, item, or service that is the subject of the qualifying clinical trial. Other non-covered items and services include:

- Services not otherwise covered by the Medicaid program;
- Items or services provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that are not used in the direct clinical management of the beneficiary; and
- Items and services provided by the trial sponsor without charge.

Qualifying Clinical Trial

A qualifying clinical trial is defined to include 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. A qualifying clinical trial must also be one or more of the following:

- A study or investigation that is approved, conducted, or supported (including funding through in-kind contributions) 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; and
  - A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants.
- A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review in compliance with Section 210 of the Consolidated Appropriations Act:
  - The Department of Energy
  - The Department of Veterans Affairs
  - The Department of Defense
- A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; or
- A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

Determination for Coverage

Determination for coverage of costs associated with a beneficiary participating in a qualifying clinical trial shall be made with the following considerations:

- Expedited and completed within 72 hours;
- Made without limitation on the geographic location of where the clinical trial is conducted or based on the network affiliation of the principal investigator or provider treating the beneficiary in connection with the clinical trial;
- Based on attestation of the provider or principal investigator regarding the appropriateness of the qualifying clinical trial; and
- Shall not require the submission of protocols of the qualifying clinical trial or any other documentation that may be proprietary.

Not all services and costs associated with a clinical trial require prior authorization (PA). All PA requirements that apply to services provided outside of a clinical trial apply to routine services within a clinical trial. (Refer to the MDHHS Medicaid Provider Manual for additional information related to PA processes and requirements.)

Claims for Services

All claims for routine patient costs associated with participation in a clinical trial must include the National Clinical Trial (NCT) number and an ICD-10 diagnosis code indicating the services are associated with a clinical trial, such as Z00.6 (encounter for examination for normal comparison and control in clinical research program). Practitioners and institutional providers must enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. Each line must be identified with the appropriate Healthcare Common Procedure Coding System (HCPCS) Modifier Q0 or Q1 as applicable.

- HCPCS Modifier Q0 - **investigational clinical service** provided in a clinical research study that is in an approved clinical research study
- HCPCS Modifier Q1 – **routine clinical service** provided in a clinical research study that is in an approved clinical research study

UB04

- Report Z00.6 in the primary or secondary position.
- Report condition code 30 whether all services are related to the clinical trial or not.
- For paper/direct data entry, report the clinical trial number in Field Locators (FL) 39-41 for value code D4.
- For electronic claim 837I, report the clinical trial number in Loop 2300 REF02 (REF01=P4).
- Outpatient and FQHC/RHC/THC claims must also include, on each claim line, the appropriate HCPCS modifiers, including Q0 or Q1.

CMS 1500/837 Professional Claim Format

- For paper/direct data entry, report the clinical trial number in FL 19
- For electronic claim form 837, report the clinical trial number in Loop 2300 NTE

Reporting Non-Covered Services

Generally, services, investigational drugs, or items that are part of the clinical trial and considered experimental or investigational should not be reported on a claim. In instances when claims processing edits require non-covered services be billed with their associated procedures, or when it is necessary for a provider to show the items and services provided free-of-charge to receive payment for the covered routine costs, providers are instructed to report non-covered services as follows:

- Inpatient Hospital Claims

  Submit non-covered services/charges on a Type of Bill (TOB) 0110 (no-pay claim). The non-covered claim must be billed with the same Statement Covers Period (From and Through date) as the payable TOB 011X submitted for the same stay as the covered services related to the clinical trial. Include the clinical trial identifiers listed above on the no-pay claim. Claims submitted with TOB 0110 will result in a denial.

- Outpatient Hospital Claims

  Report non-covered services/charges with the appropriate modifier and a token charge ($1) for a ‘no cost’ item in the covered charge field.

- Professional Claims

  Report the non-covered investigational service with the appropriate modifier and a charge of $0.