Managed Care Operations Memorandum
General Operations
MCOPS Memo # 01/2024-001

Date: January 3, 2024

Subject: Payment for Services Associated with Qualifying Clinical Trials

To: All Physical Health HealthChoices Managed Care Organizations (PH-MCOs)

From: Gwendolyn Zander, Director, Bureau of Managed Care Operations, Office of Medical Assistance Programs

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Purpose:

To advise PH-MCOs of coverage responsibilities for services associated with qualifying clinical trials.

Background:

Historically, the Medicaid statute and its implementing federal regulations did not require coverage of routine costs associated with clinical trials even if those routine costs were for items and services that would ordinarily be covered by a state's Medicaid program. This gave states the flexibility to limit or exclude coverage for routine costs associated with clinical trials. On October 30, 2000, CMS issued a State Medicaid Director Letter (SMDL), "National Coverage Decision for Costs Related to Participation in Clinical Trials" (https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/smd103000.pdf), advising states that Medicare was required to pay for routine patient care costs and costs due to medical complications associated with participation in clinical trials. This SMDL also explained that Medicaid programs could pay for otherwise covered routine costs associated with clinical trials, and that if they did, Medicare was now a liable third-party payor.

Pennsylvania's Medical Assistance (MA) Program has provided coverage for routine patient care costs for beneficiaries participating in clinical trials. This has included the coverage of any item or service covered in the Medicaid State Plan that would otherwise be covered outside of their participation in the clinical trial.

On December 28, 2023, the Pennsylvania Department of Human Services issued MA Bulletin 99-23-10, which outlined the process for providers to seek payment for routine patient care for beneficiaries participating in clinical trials when covered by the fee-for-service delivery system.

Discussion:

The Consolidated Appropriations Act of 2021, which was signed into law on December 27, 2020, amended Section 1905(a) of the Social Security Act (Act) to require the coverage of routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials.

On December 9, 2021, CMS issued a State Medicaid Director Letter (SMD# 21-005) addressing payment of routine patient costs associated with participation in qualifying clinical trials. SMD# 21-005 also explained that under Section 1905(gg)(2) of the Act, a qualifying clinical trial is 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, and is one of the following:

- A study or investigation that is approved, conducted, or supported (including by 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
    - The Agency for Health Care Research and Quality
    - The Centers for Medicare & Medicaid Services
    - A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs
    - A qualified non-governmental research entity identified in the guidelines issued by the NIH for support of 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 that the Secretary determines comparable to the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:
    - 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 Services Act; or
- A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

SMD# 21-005 describes the routine patient costs that must be covered for a beneficiary participating in a qualifying clinical trial are any items or services provided to the individual under the qualifying clinical trial, including any items or services 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. The routine services and 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. Sections 1905(a)(30) and 1905(gg)(1) of the Act.

Additionally, SMD# 21-005 explained that according to Section 1905(gg) of the Act, routine patient 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. Routine patient cost also does not include any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise covered under the state plan, waiver, or demonstration project.

SMD# 21-005 further indicated that a determination about coverage for a beneficiary participating in a qualifying clinical trial must be expedited and completed with 72 hours and based on an attestation regarding the appropriateness of the qualifying clinical trial. The attestation would be made by the health care provider and principal investigator using a form developed by CMS.

CMS subsequently released the form titled, “Medical Attestation Form on the Clinical Appropriateness of the Qualified Clinical Trial”. CMS requires all Medicaid programs to utilize this form when making coverage determinations related to the coverage of routine patient costs associated with participation in qualifying clinical trials.

The MA Fee For Service Program will be covering routine patient costs associated with participation in qualifying clinical trials consistent with SMDL# 21-0005, as announced in MA Bulletin 99-23-10. Section V.A.1. of the HealthChoices Agreement requires that PH-MCOs “provide In-Plan Services in the amount, duration and scope set forth in the MA FFS Program.” Therefore, PH-MCOs must provide coverage of routine patient costs associated with participation in qualifying clinical trials as well.

Next Steps:

Effective with the issuance of this Operations Memorandum, PH-MCOs must cover routine services associated with participation in qualifying clinical trials when the rendering provider submits to the PH-MCO documentation that indicates that coverage is appropriate. The PH-MCO may utilize the attached form, “Medical Attestation Form on the Clinical Appropriateness of the Qualified Clinical Trial,” which will be utilized by the MA Fee For Service Program, or may utilize an alternative form that contains, at a minimum, the following information:

- The name of the qualifying clinical trial's Principal Investigator
- The name or subject of the qualifying clinical trial
- The Member's name, date of birth, and Member ID number
- A link to information pertaining to the qualifying clinical trial on a publicly available website

If the PH-MCO elects to use a form other than the attachment to this Operations Memorandum, the PH-MCO may not make coverage dependent on the submission of the protocols of the qualifying clinical trial or any proprietary information.

The PH-MCO must retain the documentation in the Member's records pursuant to the records retention requirements in the HealthChoices Agreement and may not require the Principal Investigator to submit the same attestation form multiple times for services pertaining to the same qualifying clinical trial for a single Member. To the extent that the rendering provider does not participate in the PH-MCO's provider network, the PH-MCO must pay for these services on an out-of-network basis.

The PH-MCO must make coverage decisions within 72 hours of receipt of the required documentation.

The PH-MCO must review and update the following as needed in order to comply with the requirements of this Operations Memorandum:

1. Relevant coverage policies and documents, including member handbooks, which must align with the version of the Model Member Handbook included as Exhibit DD to the 2024 HealthChoices Agreement.
2. Relevant prior authorization policies, which must be submitted for departmental approval through the Prior Authorization Review Process if amended.
3. Utilization Management timelines and processes to ensure that coverage decisions will be rendered within 72 hours of receipt of documentation.
4. Claims processing systems, to ensure that claims for routine services associated with participation in qualifying clinical trials will not be denied.
5. Processes for evaluating coverage of these services.
6. Recordkeeping systems to accommodate the attached form.
7. Provider education and outreach materials, as well as provider service center scripts, to educate providers about the need to use the attached form.

Obsolete:

This MC OPS memo will remain in effect until it is superseded.

ATTACHMENT:

Medical Attestation Form on the Clinical Appropriateness of the Qualified Clinical Trial

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 principal investigator) *(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.