MetroPlus Health

Policy and Procedure

Title: Clinical Trial Coverage of Routine Care	Division: Medical Management Department: Utilization Management
Approval Date: 11/29/2022	LOB: Medicaid, HIV SNP, CHP, MetroPlus Gold, GoldCare I&II, Market Plus, Essential, HARP
Effective Date: 11/29/2022	Policy Number: UM-MP343
Review Date: 12/27/2023	Cross Reference Number:
Retired Date:	Page 1 of 6

1. POLICY DESCRIPTION:

Beginning January 1, 2014, the Affordable Care Act (ACA) required group health plans to provide coverage for routine patient costs incurred by a qualifying individual participating in an approved clinical trial. The ACA stipulates that coverage may be subject to the limitations and requirements set forth in a member's benefit plan documents.

Pursuant to section 1905(a)(30) and 1905(gg) (1) of the Social Security Act, for items and services furnished on or after January 1, 2022, routine patient costs must be covered for a Medicaid beneficiary participating in a qualifying clinical trial. These costs include any item or service provided to the individual under the qualifying clinical trial, including 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.

2. RESPONSIBLE PARTIES:

Claims Department, Integrated Care Management, Medical Management Administration, Pharmacy, Providers Contracting, Utilization Management.

3. DEFINITIONS:

Approved Clinical Trial - a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition.

Life-threatening condition - any condition or disease from which the likelihood of death is probable unless the course of the disease is interrupted.

Qualifying Individual - a member who is eligible to participate in a trial, per trial inclusion criteria, AND

- Has been referred to the trial by a participating provider who judges the member's participation as appropriate, OR
- Has self-referred to the trial and provides medical and scientific information that establishes their participation is appropriate and consistent with the trial protocol.

For Medicaid members, a qualifying individual is determined by the NY State Human Resources Administration (HRA), as described in this policy.

Routine Patient Costs - all medically necessary health care provided to the individual for purposes of the trial that are:
1- consistent with a plan's medical coverage, and
2- services that would be covered for those not enrolled in clinical trials. Such services include those rendered by a physician, diagnostic or laboratory tests, and other services provided during the course of treatment for a condition or one of its complications that are consistent with the usual and customary standard of care. Routine costs in clinical trials include:

A. Items or services that are typically provided absent a clinical trial (e.g., conventional care).
B. Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
C. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis, monitoring, or treatment of complications.

4. POLICY:

MetroPlusHealth covers all "routine patient costs" associated with the individual's participation in a clinical trial, as defined above.

Routine patient costs do not include the actual device, equipment or drug that is being studied. Additionally excluded from coverage are items and services that are provided solely to satisfy data collection and analysis needs that are not used in direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); or a service that is clearly inconsistent with the widely accepted and established standards of care for a particular disease or condition.

All of the following limitations apply to the coverage of routine costs:

A. All applicable plan limitations for coverage of out-of-network services will apply to routine patient care costs in clinical trials; and
B. All utilization management rules and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials; and

C. All applicable plan requirements for precertification and referrals must be met; and
D. All clinical trials must be approved by all relevant institutional review boards (IRBs) before participants are enrolled. Providers will not routinely be required to submit documentation about the trial to MetroPlusHealth, but the Plan can, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approval(s).

Medicaid Line of Business (Medicaid, HIV SNP, HARP)

A. The *Medicaid Attestation Form on the Appropriateness of Qualified Clinical Trial*, must be submitted to the NYS Department of Health (DOH) for each Medicaid member enrolled in a qualified clinical trial for whom Medicaid reimbursement is requested, prior to providing treatment in the trial. Once a completed form is received, the DOH will review the attestation and make a coverage determination within 72 hours of its electronic submission. Notification of the coverage determination will be sent electronically to the submitter and the Plan within 72 hours.
B. MetroPlusHealth will require proof of this coverage determination by the HRA before evaluating coverage of routine services rendered as part of a clinical trial.

5. LIMITATIONS/ EXCLUSIONS:

Routine patient costs do not include the actual device, equipment or drug that is being studied. Also excluded are items and services that are provided solely to satisfy data collection and analysis needs that are not used in direct clinical management of the patient; or a service that is clearly inconsistent with the widely accepted and established standards of care for a particular disease or condition.

a. Items and services customarily provided by the trial sponsor without any charge.

b. Benefits for routine patient care services provided outside of the plan's network area.

c. Travel, lodging, and meals are not covered.

d. Routine services coverage for all other clinical trials when the member does not have cancer or other life-threatening disease or condition. These services would be subject to standard preauthorization and utilization review standards.

6. REFERENCES:

MEDICAID ATTESTATION FORM ON THE APPROPRIATENESS OF THE QUALIFIED CLINICAL TRIAL
Medicaid Attestation Form on the Appropriateness of Qualified Clinical Trial

New York State Medicaid Update - July 2022 Volume 38 - Number 8
https://www.health.ny.gov/health_care/medicaid/program/update/2022/no08_2022-07.htm

CMS State Medical Director Notice (SMD #21-005) UPDATED: Mandatory Medicaid Coverage of Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials
https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf

National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&ncdver=2&fromdb=true

42 U.S. Code § 300gg–8 - Coverage for individuals participating in approved clinical trials
https://www.law.cornell.edu/uscode/text/42/300gg-8

REVISION LOG:

REVISIONS	DATE
Creation date	11/29/2022
Annual Review	12/27/2023

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Approved: **Date:**	**Approved:** **Date:**
Glendon Henry Digitally signed by Glendon Henry Date: 2023.12.29 08:37:45 -05'00'	Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.12.29 16:09:20 -05'00'
Glendon Henry, MD **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, MetroPlus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or

supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government, or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication. MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.