MetroPlus Health

Policy and Procedure

Title: Clinical Trial Coverage - Medicare	Division: Medical Management Department: Utilization Management
Approval Date: 12/27/2023	LOB: Medicare, UltraCare
Effective Date: 1/1/2024	Policy Number: UM-MP349
Review Date:	Cross Reference Number:
Retired Date:	Page 1 of 5

1. POLICY DESCRIPTION:

Investigational Device Exemption (IDE) Studies- MetroPlus is responsible for payment of claims related to members' participation in both Category A and B IDE studies that are covered by the Medicare Administrative Contractor (MAC) with jurisdiction over the Plan's service area. The Plan is responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. The Plan is also responsible for CMS-approved Category B devices. Category A devices will not be covered because they are statutorily excluded from coverage.

Clinical Studies Approved Under Coverage with Evidence Development (CED)- In National Coverage Determinations (NCDs) requiring CED, MetroPlus covers items and services in CMS-approved CED studies.

For clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD) (NCD manual, Pub. 100-03, Part 4, section 310), original Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in MetroPlus Medicare Advantage Plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials.

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.

Clinical Studies Approved Under Coverage with Evidence Development (CED) - refers to items and services in clinical research trials for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a "reasonable and necessary" determination.

Investigational Device Exemption (IDE) Studies- an investigational device used in a clinical study in order to collect safety and effectiveness data.

- Category A IDE devices are considered experimental and are not covered by Medicare. Category A devices must not be billed to the Plan.

- Category B IDE devices have been granted an FDA approved Investigational Device Exemption (IDE). Category B devices are eligible for coverage.

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

Routine Patient Costs - all medically necessary health care provided to the individual for purposes of the trial that are:

- Consistent with a plan's medical coverage, and
- 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:
    - Items or services that are typically provided absent a clinical trial (i.e., conventional care).
    - 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
    - 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:

Investigational Device Exemption (IDE) Studies

A. MetroPlus requires prior authorization of services related to enrollees' participation in both Category A and B IDE studies.
B. MetroPlus is responsible for the payment of CMS-approved Category B devices. Category A devices are excluded from coverage.
C. Providers submitting a request for Plan coverage should include the NCT Number (National Clinical Trial Number) or the IDE number with the authorizations request.
D. A listing of Category A&B devices, which includes the NCT and IDE number is found on the CMA Approved IDE Studies webpage: https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved

Clinical Studies Approved Under Coverage with Evidence Development (CED)

A. MetroPlus requires prior authorization of services provided in CMS-approved CED studies.
B. The National Coverage Determinations (NCDs) requiring CED include a listing of approved studies. Only approved studies are covered. Approved CED studies are posted on the CMS Coverage with Evidence Development webpage: https://www.cms.gov/medicare/coverage/evidence

Clinical Trials covered under NCD 310.1 - Routine Costs in Clinical Trials

A. Original Medicare covers all costs associated with all other clinical trials covered under NCD 310.1, including the routine costs of a qualifying clinical trials.
B. MetroPlus provides coverage for
    a. Services to diagnose conditions covered by clinical trial services.
    b. Most services furnished as follow-up care to clinical trial services and services already covered by the MetroPlus.
C. MetroPlus does not require prior authorization but does request notification in advance when a member chooses to participate in a Medicare-qualified clinical trial.

5. LIMITATIONS/ EXCLUSIONS:

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.

6. REFERENCES:

Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections, Section 10.7- Clinical Trials
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.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

Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development

https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27

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	12/27/2023
Annual Review	

Approved: Glendon C. Henry Digitally signed by Glendon C. Henry Date: 2024.01.03 07:19:17 -05'00' **Date:**	**Approved:** Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2024.01.19 13:38:56 -05'00' **Date:**
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.