Policy Number: PA.078.MPC
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

PA.078.MPC – Clinical Trials

Maryland Physicians Care considers routine care costs of members in **Clinical Trials** medically necessary for the following indications:

- The member is a participant in a qualifying clinical trial
- Documentation of 8-digit clinical trial number on items or services provided in clinical trial (Clinical trials that are also an Investigational Device Exemptions (IDE) must document associated IDE number).
- Items or services for which coverage is requested are typically provided to members who are not part of a clinical trial.
- Treatment with the items or services is included in medical record documentation of the provider(s).

Limitations

Coverage will not include any of the following:

1. The investigational item or service itself unless otherwise covered outside of the clinical trial.
2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in a direct clinical management of a patient (e.g., monthly CT scans for a condition usually requiring only a single scan).
3. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
4. Services that are not health care services (e.g., administrative services).
5. Services not routinely provided for the direct clinical management of the patient. The services must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic benefit.
6. Coverage of routine care costs for members participating in clinical trials at out-of-network facilities is governed by the benefit design of the member's plan.

Background

Clinical trials have recognized value in expanding medical knowledge and can lead to new and more effective medical treatments. Historically, the elderly have been underrepresented in clinical trials. To encourage greater participation of older Americans in research, CMS published the Clinical Trial Policy (CTP) National Coverage Determination (NCD) in response to a Presidential Executive Memorandum concerning payment for routine costs incurred by Medicare beneficiaries participating in clinical trials in 2000. That policy was based on the statutory authority of Section 1862(a)(1)(E) of the Social Security Act. In July 2006, CMS began a reconsideration of that 2000 NCD to address several issues about the policy. The CMS NCD for Routine

PA.078.MPC - Clinical Trials- Coverage of Routine Care Costs

Policy Number: PA.078.MPC
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

Costs in Clinical Trials (310.1) has been updated July 9, 2007 and was used for the general basis of this policy along with all other terms, conditions, and standards that are defined.

Trials conducted under an Investigational New Drug (IND) application reviewed by the United States Food and Drug Administration (FDA) and drug trials that are exempt from having an IND will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain coverage of routine costs. The certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status. Other clinical trials that are deemed to be automatically qualified include those either funded by or supported by centers or cooperative groups that are funded by NIH, Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DOD), and Department of Veterans Affairs.

Clinical trials also should have the following desirable characteristic:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

References

1. Centers for Medicare and Medicaid Services (CMS), Medicare Coverage Database. Decision Memo for Clinical Trial Policy (CAG-00071R). July 9, 2007. Found at: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=186&NcaName=Clinical+Trial+Policy&NCDId=1&IsPopup=y&bc=AAAAAAAACAAAAA%3D%3D&

2. Centers for Medicare and Medicaid Services, National Coverage Determination (NCD) – No. 310.1 - Routine Costs in Clinical Trials. Effective July 9, 2007. Implementation Date: Oct 10, 2007. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&
3. Centers for Medicare and Medicaid Services (CMS), Medicare Learning Network (MLN) – MLN Matters No. MM8401 – Revised. Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims. Revised June 9, 2014.http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf
4. Centers for Medicare and Medicaid Services (CMS), Medicare Learning Network (MLN). MLN Matters No. SE0822 Revised -Clarification of Medicare Payment for Routine Costs in a Clinical Trial. Revised on May 16, 2018. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE0822.pdf
5. Centers for Medicare and Medicaid Services (CMS), Medicare Learning Network (MLN), MLN Matters No. MM3548 - Coverage of Routine Costs of Clinical Trials Involving Investigational Device Exemption (IDE) Category A Devices. Effective: 01/01/2005. Last Updated: 05/12/2013. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R131OTN.pdf
6. National Institutes of Health-Office of Extramural Research: Glossary & Acronym List, Last updated March 20, 2013. http://grants.nih.gov/grants/glossary.htm
7. United States of America. Federal Government: Public Law 111-152. Health Care and Education Reconciliation. Enacted: March 30, 2010. http://www.gpo.gov/fdsys/pkg/PLAW-111publ152/pdf/PLAW-111publ152.pdf
8. U.S. Department of Labor (DOL). Employee Benefits Security Administration (EBSA). FAQs about the Affordable Care Act Implementation Part XV. Coverage for Individuals Participating in Approved Clinical Trials - Q3. Posted: April 29, 2013. https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xv.pdf

Disclaimer:
Maryland Physicians Care medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of Maryland Physicians Care and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

Maryland Physicians Care reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.