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PA.078.MPC Clinical Trials

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

General Requirements (1-4)

- The member is a participant in a qualifying clinical trial. NOTE: Documentation confirming enrollment in the clinical trial must be submitted along with the participation request.
- 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).

Federally Funded Trials (5)

- 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.

Limitations

Coverage will not include any of the following:

- The investigational item or service itself unless otherwise covered outside of the clinical trial.

- 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).
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
- Services that are not health care services (e.g., administrative services).
- 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.
- 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.

References

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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.