MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

Policy Number: PA.078.MH
Last Review Date: 11/08/2018
Effective Date: 01/01/2019

PA.078.MH – Clinical Trials- Coverage Routine Care Costs

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers routine care costs of members in clinical trials medically necessary for the following indications:
1. The member is a participant in a qualifying clinical trial
2. 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).
3. Items or services for which coverage is requested are typically provided to members who are not part of a clinical trial.
4. 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.

Note: See PA-079 - Experimental and Investigative Services regarding coverage of Investigational Device Exemptions (IDE) and Humanitarian Use Devices (HUD).

PA.078.MH – Clinical Trials- Coverage of Routine Care Costs

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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 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.

Variations - for Commercial Self-Funded (ASO) groups:
The applicability of this policy to individuals in self-funded commercial groups is subject to the contractually agreed upon Schedule of Benefits associated with the specific coverage/plan design that each self-funded group has purchased. Whether coverage/payment for the services and/or benefits governed by this policy are available to a self-funded group member is determined on a case by case basis, based on the benefit plan of that member's Schedule of Benefits and, unless expressly stated otherwise, any authorization/medical necessity requirements described herein.

Medicare: Clinical trials must meet the following three requirements:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery)

2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers.

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.

For Commercial Self-Funded (ASO) groups:
The applicability of this policy to individuals in self-funded commercial groups is subject to the contractually agreed upon Schedule of Benefits associated with the specific coverage/plan design that each self-funded group has purchased. Whether coverage/payment for the services and/or benefits governed by this policy are available to a self-funded group member is determined on a case by case basis, based on the benefit plan of that member's Schedule of Benefits and, unless expressly stated otherwise, any authorization/medical necessity requirements described herein.

For Commercial Members in the State of Maryland:

In the state of Maryland, patient costs associated with a clinical trial are covered as follows:

"Patient cost" means the cost of a medically necessary health care service that is incurred as a result of the treatment being provided to the member for purposes of the clinical trial.

"Patient cost" does not include:

- the cost of an investigational drug or device;

- the cost of nonhealth care services that a member may be required to receive as a result of the treatment being provided for purposes of the clinical trial;
- costs associated with managing the research associated with the clinical trial; or
- costs that would not be covered under the member's policy, plan, or contract for noninvestigational treatments.

This section applies to:

(1) members insured byinsurers and nonprofit health service plans that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups on an expense-incurred basis under a health insurance policy or contract issued or delivered in the State; and

(2) health maintenance organizations that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups under contracts that are issued or delivered in the State.

(3) This section does not apply to a policy, plan, or contract paid for under Title XVIII or Title XIX of the Social Security Act.

A policy, plan, or contract subject to this section shall provide coverage for patient cost to a member in a clinical trial, as a result of:

(1) treatment provided for a life-threatening condition; or

(2) prevention, early detection, and treatment studies on cancer.

Coverage for patient costs is required if:

(i) the treatment is being provided or the studies are being conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer; or

(i) the treatment is being provided in a Phase I, Phase II, Phase III, or

(ii) the treatment is being provided in a Phase I, Phase II, Phase III, or Phase IV clinical trial for any other life-threatening condition;

(3) the treatment is being provided in a clinical trial approved by:

(i) one of the National Institutes of Health;

(ii) an NIH cooperative group or an NIH center;

(iii) the FDA in the form of an investigational new drug application;

(iv) the federal Department of Veterans Affairs; or

(v) an institutional review board of an institution in the State which has a multiple project assurance contract approved by the Office of Protection from Research Risks of the National Institutes of Health;

(4) the facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise;

(5) there is no clearly superior noninvestigational treatment alternative; and

(6) the available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative.

Additionally' a policy, plan, or contract shall provide coverage for patient cost incurred for drugs and devices that have been approved for sale by the FDA whether or not the FDA has approved the drug or device for use in treating the patient's particular condition, to the extent that the drugs or devices are not paid for by the manufacturer, distributor, or provider of that drug or device.

Note: This section may not be construed to affect compliance with § 15-804 of this subtitle regarding coverage for off-label use of drugs.

References

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Disclaimer:
MedStar Health 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 MedStar Health 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.

MedStar Health 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.