MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

SUBJECT: **Clinical Trials– Coverage of Routine Care Costs**
INDEX TITLE: **Medical Management**
ORIGINAL DATE: **January 2013**

This policy applies to the following lines of business: (Check those that apply.)

COMMERCIAL	[ ] HMO	[ ] PPO	[ ] Fully Insured	[ ] Individual Product	[ ] Marketplace (Exchange)	[X] All
GOVERNMENT PROGRAMS	[ ] MA HMO	[ ] MA PPO	[ ] MA C-SNP	[ ] MA D-SNP	[X] MA All	
	[ ] Medicaid					
OTHER	[X] Self-funded/ASO					

I. POLICY

MedStar Health, Inc. will cover routine patient care costs for members enrolled in qualifying clinical trials. The coverage will generally follow the guidelines established in the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1.MH).

Costs of routine care and complications arising during participation in qualifying clinical trials will be covered according to medical necessity, member's own specific benefit plan, and all other terms, conditions, and standards defined in this Policy.

All payments are based on medical necessity and appropriateness as determined by a MedStar Health, Inc. Medical Director (Medical Director).

II. DEFINITIONS

Clinical research -- as defined by the National Institutes of Health (NIH), is research conducted by an investigator who directly interacts with human subjects. Patient-oriented research involves a particular person or group of people and includes the mechanisms of disease, therapeutic interventions, clinical trials, and development of new technologies.

Clinical trials -- are defined as protocol-based, scientific research studies designed to answer specific questions about the safety and effectiveness of new drugs, treatments, or devices, or about new uses of existing drugs, treatments, or devices. Clinical trials generally proceed through four phases, as defined below:

1. Phase I - the study drug or treatment is given to a small group (6-100) of healthy volunteers for the first time to evaluate its safety, identify side effects and determine a safe dosage range.
2. Phase II - the study drug or treatment is given to larger groups (100-300) of volunteers who have a particular disease to further evaluate its effectiveness, safety, and optimal dosage to achieve maximal benefit with the least side effects.

3. Phase III - the study drug or treatment is given to large groups of volunteers (1000-3000) who have a particular disease to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely.
4. Phase IV - post marketing large-scale (10,000), long-term trials to delineate additional information about a treatment's risks, benefits, optimal use, and effects in various patient populations.

Qualifying Clinical Trials -- are defined as research studies that are eligible for coverage of routine care costs. These studies are only considered to qualify if they meet all of the eligibility requirements listed below:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category (e.g., physician service, durable medical equipment, diagnostic test) and is not excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial must have a therapeutic intent and not be solely designed to test toxicity or disease pathophysiology.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
4. The principal purpose of the trial is to test whether the intervention potentially improves the participant's health outcomes.
5. 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.
6. The trial does not unjustifiably duplicate existing studies.
7. The trial design is appropriate to answer the research question asked of the trial.
8. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully.
9. The trial must have a written protocol and be approved by an applicable, qualified institutional review board (IRB).
10. The trial is in compliance with Federal regulations relating to the protection of human subjects.
11. The trial is in compliance with Federal regulations governing patient privacy.
12. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.
13. The research study must be registered on the ClinicalTrials.gov website (http://clinicaltrials.gov/) prior to the enrollment of the first study subject.

Routine costs -- apply to participants in both experimental or control arms of qualifying clinical trials, and include medically necessary items and services that would otherwise be available to MedStar Health, Inc. members, providing the items and services:

1. Exist within a benefit category.
2. Are not statutorily excluded from coverage.
3. Are not subject to a national non-coverage decision.

Routine costs do not include any of the following:

a. The investigational drug, device, or treatment itself.

b. Items and services provided solely to satisfy data collection and analysis that are not used in the direct clinical management of the patient.
c. Services clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

III. PURPOSE

The purpose of this policy is to define the specific indications and limitations of coverage for routine care services provided for a member while participating in qualifying clinical trials.

IV. SCOPE

This policy applies to various departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description / 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 issued a NCD on September 19, 2000, requiring the coverage of routine care costs for Medicare participants of clinical trials. 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.

B. Specific Indications

MedStar Health will cover routine costs of members in clinical trials if all of the following criteria are met (Refer to Section G-Variations for exceptions):

1. The MedStar Health member is a participant in a qualifying clinical trial as defined above (Section II- Definitions and Section V- in A. Medical Description/Background).
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).

C. Limitations

Coverage will not include any of the following:

a. The investigational item or service itself unless otherwise covered outside of the clinical trial.
b. 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 scans for a condition usually requiring only a single scan).
c. Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.
d. Services that are not health care services.
e. Services not routinely provided for the direct clinical management of the patient.
f. Costs for administrative services.
g. See MP.079.MH - Experimental and Investigative Services regarding coverage of Investigational Device Exemptions (IDE) and Humanitarian Use Devices (HUD).
h. 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.

D. Information Required for Review

In order for medical necessity to be established, adequate information must be furnished by the treating physician upon request of MedStar Health. Necessary documentation includes, but not limited to the following:

- Member's age and clinical history
- Documentation of diagnosis and treatment history
- Clinical Trial/research study name, Clinical Trial/research study sponsor and numeric registry number
- Clinical Trial protocol
- Current IRB approval letter

- A copy of the FDA approval with the scope of the indication that was approved (if applicable)
- The Fiscal Review Form which indicates the name of the device, the sponsor and line item listing of services paid by the sponsor of the study/trial.
- The member's informed, signed consent to participate in the study.

E. Review Process

1. The Medical Management ancillary service staff reviews the request according to the established criteria. If the case does not meet the established criteria, it is referred to a MedStar Health, Inc. Medical Director (Medical Director).
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management ancillary service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

F. Documentation required for claims payment

- **Code V70.7 (ICD-10 Code Z00.6) reported as primary or reported as the secondary diagnosis**
- Utilization of appropriate HCPCS modifiers Q0 and Q1

G. Variations

For the Medicaid products –
Clinical Trials are a non-covered benefit for CHIP and Medicaid members as well as procedures, technologies, treatments, equipment and devices that are used as a necessary accompaniment to Clinical Trials.

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 from any entity within the UPMC Insurance Services Division. 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.

(c) 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:

(1) (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

(ii) 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;

(2) 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;

(3) 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;

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

(5) 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.

H. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc., and as indicated in the MedStar Health, Inc. Division Policy and Procedure CORP.028.MH Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

I. References

Regulatory/Government Source:

1. Centers for Medicare and Medicaid Services (CMS), Medicare Coverage Database. Decision Memo for Clinical Trial Policy (CAG-00071R). Dated: July 9, 2007Found 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. 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. Effective January 1, 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 January 7, 2009. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE0822.pdf
5. 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
6. National Institutes of Health-Office of Extramural Research: Glossary & Acronym List, Updated March 20, 2013. http://grants.nih.gov/grants/glossary.htm
7. 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/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM3548.pdf

8. Maryland State Mandate: Maryland Code of Law §15-827: Clinical Trials http://www.mdinsurance.state.md.us/sa/docs/documents/consumer/publicnew/mandatedbenefits.pdf
9. Maryland Essential Health Benefits: Clinical Trials: http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/md-state-required-benefits.pdf