

UPMC Health Plan POLICY AND PROCEDURE MANUAL

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SUBJECT: Clinical Trials (Commercial only)
INDEX TITLE: Medical Management
ORIGINAL DATE: December 2008

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

COMMERCIAL:				
HMO ()	POS ()	PPO ()	OOA ()	
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)	
Medicare Select ()	Medicare Supplement ()	Individual Product ()		
DPW-MA:				
Health Choices ()	Voluntary ()		All ()	
CMS-MA:				
OH ()	WV ()	PA ()	All ()	Other ()
HMO ()	PPO ()	Specialty Needs Plan ()	Part D ()	PFFS ()
PID-CHIP/AdultBasic:				
Free () CHIP only	Sub/CHIP ()	Sub/AB ()	Full/CHIP ()	Full/AB ()
All/CHIP () All/AB ()				
ANCILLARY:				
Dental ()	Vision ()			
APPLICABLE TO:				
Community Care ()	Work Partners ()			

I. POLICY

It is the policy of UPMC Health Plan to recognize the value of clinical research trials which evaluate and compare the safety and efficacy of new untested or non-standard treatments to currently acceptable standard treatments and which are key to understanding the appropriate use of medical interventions of all types. Coverage for medically necessary routine clinical services will be considered when it is medically necessary and covered under the member's benefit plan.

UPMC Health Plan members enrolled in clinical trials must be informed that they may be receiving standard treatment, investigational treatment, placebo treatment or no treatment.

All denials are based on medical necessity and appropriateness as determined by a UPMC Health Plan Medical Director (Medical Director).

II. DEFINITIONS

Clinical research is the observation of events in a group of individuals who share a particular characteristic, such as a symptom or illness or who have the same treatment or diagnostic test provided for a symptom or illness.

Clinical trials are research studies designed to evaluate the safety and effectiveness of medical care, to improve clinicians' knowledge about a treatment and to improve clinical outcomes for future patients.

Clinical trials generally proceed through four phases:

1. Phase I - the study drug or treatment is given to a small group of people for the first time to evaluate its safety, determine a safe dosage range and to identify side effects
2. Phase II - the study drug or treatment is given to a large group of people to see if it is effective and to further evaluate its safety
3. Phase III - the study drug or treatment is given usually to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the drug or treatment to be used safely
4. Phase IV - studies performed after the drug or treatment has been marketed to collect information about its effects in various populations and any side effects associated with long-term use.

Routine costs of a clinical trial include all items and services that are otherwise generally available to UPMC Health Plan members and include all of the following:

- there exists a benefit category;
- it is not statutorily excluded; and
- there is not a UPMC Health Plan non-coverage decision.

These routine costs may be provided in either the experimental or the control arms of a clinical trial.

III. PURPOSE

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

IV. SCOPE

This policy applies to various UPMC Health Plan 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 serve as the first step toward providing new clinical innovations to the forefront of medical practice. The knowledge gained from clinical trials could lead to the development of new therapies and better health care. Over the last decade the Centers for Medicare and Medicaid Services (CMS) has provided coverage of routine health care costs of Medicare beneficiaries in clinical trials. Medicare has since expanded its definition of coverage to encourage the greater use of clinical trials by older Americans. As such, these guidelines are generally followed for the Commercial product as described in this policy.

Clinical Trial Requirements include all of the following:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a UPMC Health Plan benefit category (e.g., physician service, durable medical equipment, diagnostic test) and is not excluded from coverage (e.g., cosmetic surgery).
- The trial must have a therapeutic intent.
- 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.
- The trial must be approved by applicable, qualified institutional review boards.
- The trial must be conducted in a setting and by personnel that maintain a high level of expertise because of their training, experience, and volume of patients.

Clinical Trial General Standards include all of the following:

- The principal purpose of the trial is to test whether the intervention potentially improves the participant's health outcomes;
- 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;
- The trial does not unjustifiably duplicate existing studies;
- The trial design is appropriate to answer the research question being asked in the trial;
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
- The trial is in compliance with Federal regulations relating to the protection of human subjects; and
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity.
- The clinical study must have a written protocol.

Clinical Trial Specific Standards include all of the following:

- The research study must be registered on the Clinical Trials.gov website prior to the enrollment of the first study subject.
- The research study protocol must specify and fulfill method and timing of public release of results.
- The research study must have explicitly discussed inclusion criteria and considered relevant subpopulations (as defined by age, gender, race/ethnicity, socioeconomic, or other factors) in the study protocol.
- The protocol must contain a discussion of how the results will generalize to our member population.

Clinical trial eligibility:

To promote the safety of UPMC Health Plan members, clinical trials must meet the specified eligibility criteria above for the protection of our participating members before consideration of coverage for routine clinical services.

Trials conducted under an Investigational New Drug (IND) application reviewed by the 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.

B. Specific Indications

UPMC Health Plan will cover the routine clinical services of **qualifying** clinical trials (i.e., those clinical trials which meet the eligibility criteria set forth above) as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. Routine costs of a clinical trial include all items and services generally available to UPMC Health Plan members (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a UPMC Health Plan non-coverage decision) such as:

- Items or services that are typically provided absent a trial (e.g., conventional care) and
- Providers must maintain in their medical record documentation and have available upon request an informed signed consent from the member

C. Limitations

UPMC Health Plan will not consider for coverage any of the following:

- The investigational item or service itself unless otherwise covered by UPMC Health Plan.
- 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).
- 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.
- Services not routinely provided for the direct clinical management of the patient.
- Costs for administrative services.
- See UPMC MP.079 - Experimental or Investigative Services regarding coverage of Investigational Device Exemptions (IDE) and Humanitarian Use Devices (HUD).
- **All applicable plan limitations for coverage of out-of-network care will apply to routine care costs in clinical trials**

D. Information Required for Review

In order for medical necessity to be established, adequate information must be furnished by the treating physician. Necessary documentation includes the following:

- Member's age and clinical history
- Documentation of diagnosis and treatment history
- Clinical Trial name, Clinical Trial sponsor and eight-digit numeric registry number
- Clinical Trial protocol
- The IRB (Institutional Review Board) approval letter
- A copy of the FDA approval with the scope of the indication that was approved (if applicable)
- An invoice from the manufacturer for the IDE/HUD which indicates the charge for the device does not exceed the cost of the device to the researcher/facility
- 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

E. Review Process

1. The Medical Management staff assigned to review obtains the clinical information to determine if there is adequate clinical information. If the case does not meet the established criteria, it is referred to a UPMC Health Plan Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.

3. The Medical Management 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. Variations

For the Medicare product –

Claims for routine costs of Clinical Trials for Medicare members should be submitted directly to Original Medicare and not to UPMC Health Plan

For the CHIP and Medical Assistance products –

Clinical Trials are a non covered benefit for CHIP and Medical Assistance members as well as procedures, technologies, treatments, equipment and devices that are used as a necessary accompaniment to Clinical Trials.

H. Records Retention

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

I. References

1. Centers for Medicare and Medicaid Services, Medicare Coverage Database, *Proposed Decision Memo for Clinical Trial Policy* (CAG-00071R), 04/10/2007, www.cms.hhs.gov/mcd
2. Medicare Learning Network, MLN Number MM3548, *Coverage of Routine Costs of Clinical Trials Involving Investigational Device Exemption Category A Devices*, 01/01/2005
3. Centers for Medicare and Medicaid Services, *NCD for Routine Costs in Clinical Trials* (310.1), 10/20

Disclaimer:

UPMC Health Plan 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 UPMC Health Plan 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.

UPMC Health Plan 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.

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