

UPMC Health Plan POLICY AND PROCEDURE MANUAL

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SUBJECT: Experimental and Investigational Services
INDEX TITLE: Medical Management
ORIGINAL DATE: November 2006

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

COMMERCIAL:			
HMO ()	PPO ()		All (X)
Fully Insured ()	Self-funded/ASO ()		
Indiv Short Term ()			
CMS-MA:			
OH ()	WV ()	PA ()	All (X)
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()
DPW-MA:			
Health Choices /PH ()	Voluntary ()	Health Choices/BH ()	All ()
PID-CHIP:			
CHIP only ()			
ANCILLARY:			
UPMC Dental Advantage ()	UPMC Vision Advantage ()	COBRA ()	All ()
WORK PARTNERS:			
Commercial WC ()	Disability Services/TPA ()	Health Promotion ()	All ()

I. POLICY

It is the policy of UPMC Health Plan to recognize the value of new technology or services in the diagnosis and management of disorders. UPMC Health Plan also recognizes that experimental and investigative services are important to test the validity and usefulness of any such service. Due to the fact that these services may not be fully tested and deemed to be safe, all such requests for the services listed in the appendix to this policy are deemed to be **non-covered** services. Coverage for possible exemptions will be considered when it is medically necessary and covered under the member's benefit plan.

UPMC Health Plan recognizes that certain investigative medical devices are studied as part of a Food and Drug Administration (FDA) approved clinical trial, but have not been approved for marketing. This policy establishes guidelines for review of these devices with "Investigational Device Exemptions" and those approved by the FDA under "Humanitarian Device Exemptions".

Services that are considered Experimental or Investigative are not covered by UPMC Health Plan member's (UPMC-Health Plan) individual benefit plan. In the event the Centers for Medicare & Medicaid Services (CMS) has a Local Coverage Decision (LCD)

or National Coverage Decision (NCD) in place regarding a procedure, service or device deemed experimental/investigational by UPMC-Health Plan, UPMC-Health Plan will follow the relevant LCD or NCD on that procedure, service or device for UPMC-HP Medicare Advantage Members only.

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

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define technologies, devices, procedures, injectable drugs and biologics, vaccines and medical treatments that are generally not covered, to outline the rationale behind non-coverage of such experimental and investigative services and to identify those services that have been deemed to be so.

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

Due to the rapidly developing advancements in medical care and technology, the opportunity arises to apply these cutting-edge health care options to an ever-increasing range of specialties. However, many of these new developments may still be awaiting results of clinical trials or have not been sufficiently tested to provide long-term, evidence-based outcomes which confirm safety and efficacy. Therefore, this policy lists those technologies lacking such evidence in the attached appendix.

New technologies or new applications of existing technologies may not always provide the indicated long-term outcomes that may have been intended. Emerging and adjunctive technologies are assessed by a systematic review of scientific evidence, and discussed in detail at the UPMC Health Plan's Patient Safety and Technology Assessment Committee in order to provide appropriate coverage determinations, and adequate understanding of

the medical science and its application and services involved. Recommendations from this committee are based on scientific and evidence-based evaluations of the services. These recommendations are then submitted to Senior Management for review and endorsement of those recommendations.

The UPMC Health Plan's Patient Safety Technology Assessment Committee's evaluation process encompasses a comprehensive investigation of peer reviewed literature, clinical trials, outcomes data, along with regulatory requirements and existing national guidelines. Input is also obtained from professionals with expertise in the field of service or technology being reviewed.

Services that are considered Experimental or Investigative are listed on an appendix to this policy and the appendix will be updated anytime a new service is deemed to be experimental or investigative. This list should not be considered all-inclusive.

Investigational Device Exemptions (IDE):

The U.S. Federal Food Drug & Cosmetic Act (FD&C Section 201 (h)) defines a device as follows: A device is: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

An Investigational Device Exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification (510K) submission to the FDA. Clinical studies are most often conducted to support a PMA. A small percentage of 510K's require clinical data to support the application. These also include clinical evaluation of certain modifications or newly intended uses of legally marketed devices. All such clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

For purposes of assisting CMS coverage determinations, the FDA places all approved IDEs in one of two categories:

Category A - Experimental

- Consist of novel, first-of-a-kind technologies.
- These are innovative devices for which the absolute risk of the device type has not been established and initial questions of safety and effectiveness have not been resolved.
- The FDA is unsure whether these device types can be safe and effective.

Category B – Non-Experimental/Investigational

- These are the types of devices that are newer generations of proven technologies.
- Initial questions of safety and effectiveness of these devices have been resolved.
- Devices placed in this category are considered to represent evolutionary changes in proven technologies.

Humanitarian Use Device (HUD):

An HUD is a device that is intended to benefit patients with a disease or condition that is manifested in fewer than 4000 individuals in the US per year. Approval for HUD's is obtained from the FDA under a Humanitarian Device Exemption (HDE) and this authorizes the marketing of the HUD. These devices are exempt from the effectiveness requirements of a PreMarket Approval process by the FDA. The HDE application is not required to contain results from scientifically valid clinical investigations. The application however, must contain sufficient information to indicate that the device does not pose an unreasonable or significant risk of illness or injury and that the probable benefit outweighs the risk from its use. Additionally the HDE application must demonstrate that no comparable devices are available to treat or diagnose the disease or condition.

B. Specific Indications

All of the following apply to all new technology/service requests:

- The technology must be supported by a significant body of scientific evidence supporting safe and effective long-term outcomes resulting in the same or greater health benefits than established alternatives;
- Must be approved by appropriate regulatory agencies e.g. Food and Drug Administration (FDA) for the specific intended use or purpose;
- Clinical trial outcomes must be attainable outside the investigational setting;
- Must be within currently accepted standards of good medical practice; and
- Must be appropriate in treatment for the specific diagnosis.

For devices with IDE exemptions:

Category A devices are considered experimental and therefore not considered reasonable and necessary. Routine costs of clinical trials will be covered by

UPMC Health Plan upon determination that the device is intended for the diagnosis, monitoring or treatment of an immediately life-threatening disease/condition although the device itself will be non-covered.

Category B devices: The following guidelines apply to these devices:

- The device must be used within the context of the FDA approved clinical trial.
- The device must be used according to the clinical trial's approved patient protocol.
- The medical necessity of the device must be established for the particular member and medical appropriateness established for the amount, duration, and frequency of use or applications of the service.
- Appropriateness of the setting where the service is furnished with regard to the member's medical needs and condition and benefit plan.

For devices with Humanitarian Device Exemptions (HDE):

- An HDE may only be used in facilities that have an established local IRB (Institutional Review Board) to supervise the clinical testing of the device or service.)
- The IRB approval must be up to date as per IRB requirements – i.e. annual update.

C. Limitations

The following limitations are applicable for **Category B** devices:

- When the services or technologies are in the developmental or testing stage.
- When there is no final regulatory or governmental approval.
- When the IDEs are applied in an inpatient setting, they will be included in the DRG (Diagnosis Related Group) payment.

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/research study name, Clinical Trial/research study sponsor and numeric registry number
- Clinical Trial/research study 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

Generally the CHIP and Medical Assistance products do not cover IRB studies using IDE/HUDs as these are considered research and experimental/investigative services.

G. Records Retention

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

H. References

1. Highmark Medicare Services Bulletin, Humanitarian Device Exemptions Requests- Instructions for Part A and B Providers, Revision date 06/26/2008
2. Medicare Benefit Policy Manual – Chapter 14, Medical Devices
3. US Food and Drug Administration – Clinical Trials and IDEs.
4. Medical Services Advisory Committee. (2004) *Funding for new medical technologies and procedures; application and assessment guidelines*. Available on-line: <http://www.msac.gov.au>.
5. U.S. Food and Drug Administration. (2002) *Improving innovation in medical technology: Beyond 2002*. Available on-line: <http://www.fda.gov>.
6. BlueCross BlueShield Association. (2005) *Technology evaluation center criteria*. Available on-line: <http://www.bcbs.com/tec/teccriteria.html>.
7. *Humanitarian Device Exemption (HDE) Requirements Appendix N*. <http://www.irb.pitt.edu/manual/AppendixN.pdf>
8. U.S. Food and Drug Administration: *The Humanitarian Device Exemption - Safe Medical Devices Act of 1990*, <http://www.fda.gov/orphan/humdev.htm>

9. *U.S. Food and Drug Administration: Humanitarian Device Exemption, updated February 21, 2008*
10. Highmark Medicare Services Webinar, *Medicare Part A Presents: Clinical Trials*, 09/08/2010

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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