Premier Health Plan
POLICY AND PROCEDURE MANUAL

Policy Number: PA.079.PH
Last Review Date: 08/09/2018
Effective Date: 10/01/2018

PA.079.PH – Experimental and Investigational Services

This policy applies to the following lines of business:
- ✓ Premier Employee

Premier Health Plan considers **Experimental and Investigational (E&I) Services** medically necessary for the following indications:

1. The medical service or application is supported in peer-reviewed medical literature and accepted as safe and effective by the medical community. There must be documentation of improvement if the health outcome is referenced by evidence-based medicine standards.
2. It must be approved by appropriate regulatory agencies (e.g., FDA) for the specific intended use or purpose;
3. The scientific evidence and/or clinical outcomes for the medical service and/or application are peer-reviewed and must be attainable outside the experimental or investigational setting;
4. Application of the medical service must be within accepted standards of good medical practice; and
5. The medical service and/or its application must be appropriate in the treatment of the diagnosis or condition specified in the request.

For devices with Investigational Device Exemptions (IDE):

- Category A devices will not be covered because they are considered experimental and investigational, and therefore not considered reasonable and necessary medical services. Routine care costs of patients participating in clinical trials may be covered if allowed under the member's specific benefit plan according to PA.078 Clinical Trials - Coverage of Routine Care Costs upon determination that the device is intended for the diagnosis, monitoring or treatment of an immediately life-threatening disease/condition, but the device itself will not be covered.
- Category B devices may be considered for coverage if allowed under member's specific benefit plan and all of the following apply:
    1. The device must be used within the context of the FDA approved clinical trial.
    2. The device must be used according to the clinical trial's approved patient protocol.

3. 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.
4. The setting where the service is furnished must be appropriate according to the member's medical needs, condition, and benefit plan.

For devices with Humanitarian Device Exemptions (HDE):

If appropriate under the member's specific plan, all of the following must apply for consideration of coverage for a Humanitarian Use Device (HUD) on the basis of a HDE:

1. A HUD may only be used in facilities that have an established local Institutional Review Board (IRB) to supervise the clinical testing of the device or service);
2. IRB approval for use of the HUD must be current according to the IRB requirements (e.g., updated annually);
3. The HUD must only be used for HDE approved indications specified in the product labeling.

Limitations

Category B devices will not be covered if any of the following apply:

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

The service or procedure will be considered not medically necessary if the available scientific proof does not indicate that the treatment is safe and effective for treating or diagnosing the relevant medical condition or illness or the intervention has not been shown to improve health outcomes. Information may be accessed from the following sources (not limited to):

- Current and published scientific evidence and technology literature
- Technology updates, news and summaries from Hayes, the Cochrane Collaborative or other nationally recognized organizations, such as medical experts or affected specialty societies
- Published medical literature in peer-reviewed journals
- Published opinions, actions and other relevant documents of independent external research organizations such as NIH, NCI, FDA and HHS

In addition to the above criteria, the Medical Policy Committee (MPC) will consider recommendations of national physician specialty societies, nationally recognized

professional healthcare organizations and public health agencies, and in its sole discretion, may consider other relevant factors, including information from the practicing community.

See Also:

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

Background

Category A (Experimental) device refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Non-experimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type

The Medical Policy Committee (MPC) and Evolent UM staff routinely conduct evidence-based reviews of new and emerging medical services. This assessment includes:

- A thorough review of available scientific information, which may include peer-reviewed literature, results of clinical trials, outcomes data, regulatory requirements, and input from professionals in the field of the medical service under review;
- Discussion among a multidisciplinary group of health care providers to achieve an adequate understanding of the medical science and its application;
- An appropriate coverage recommendation based on the sum of the evidence;
- Identification of medical services as "experimental and investigational" according to the definition provided in this Policy.

Services determined to be experimental and investigational are listed, and experimental and investigational services which demonstrate a significant body of scientific evidence supporting safety and effectiveness are removed from the list. If there is no documentation that the experimental and investigational service does not provide benefit, or there Is not any benefit that is equal ro better than the standard of care, it is considered to be experimental and investigational. Due to the frequency at which new

medical services are developed and researched, this list of services should not be considered all-inclusive as it has the potential to change frequently due to the body of evidence available.

Codes:

- **ICD- 10 Code Z00.6** must be reported as the secondary diagnosis
- Utilization of appropriate modifiers Q0 and/or Q1

References

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3. Centers for Medicare and Medicaid Services (CMS), Medicare Benefit Policy Manual, Chapter 4 – Payment for Investigational Device Exemption (IDE) Studies. Updated 06/16/15. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf
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6. Social Security Act. Section 1862 (42 USC 1395y). Exclusions from Medicare Coverage and Medicare as Secondary Payer. http://www.ssa.gov/OP_Home/ssact/title18/1862.htm
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12. United States Food and Drug Administration (FDA). CFR- Code of Federal Regulations Title 21. Part 807. Establishment Registration and Device Listing for Manufacturers and Initial Importer of Devices. Page Last Updated: 04/01/2017. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=807.20
13. United States Food and Drug Administration (FDA). Quality System (QS) Regulation/Medical Device Good Manufacturing Practices. Page Last Updated: 03/27/2018. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm
14. United States Food and Drug Administration (FDA). Guidance on IDE Policies and Procedures, Issued January 20, 1998. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080203.pdf

Disclaimer:
Premier 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 Premier 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.

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Premier 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.