MN.005.B

Experimental and Investigational Services, Investigational Device Exemption (IDE), and Coverage with Evidence Development (CED)

Health Partners Plans

Title: Experimental & Investigational Services, Investigational Device Exemption (IDE), and Coverage with Evidence Development (CED)
Policy #: MN.005.B
Type: Medical | **Sub-Type:** MN (Medical Necessity)

Original Implementation Date: 8/1/2016
Version Date [B]: 7/1/2018
Last Reviewed: 3/27/19

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PRODUCT VARIATIONS

This policy applies to all Health Partners Plans (HPP) product lines, unless noted below.

POLICY STATEMENT

General Criteria for Experimental/Investigational

A service or supply, including but not limited to, a drug, vaccine, treatment, device or procedure is considered **experimental or investigational** if any of the following criteria are met:

- It cannot be lawfully marketed without the approval of the Food and Drug Administration (FDA) and final approval is not granted at the time of its use or proposed use. This may include drugs or devices that:
  - Have a current new drug or new device application on file with the FDA and approval is not yet granted
  - Drugs granted orphan drug status that have not yet received approval by the FDA
- The consensus opinion in the medical literature among experts indicates:
  - Usage is appropriate only within the context of a clinical trial
  - Further research is needed to define safety, toxicity, effectiveness and comparative effectiveness to standard of care treatments
- Use of the requested service/item is dependent on a drug, device, treatment or procedure that is investigational or experimental.

Determination of experimental and investigational status will consider:

- Guidelines from nationally recognized health care organizations
- Peer-reviewed medical literature within published medical journals
- Evidence based consensus statements
- The member's unique medical circumstances as documented in the medical record

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RELATED POLICIES

N/A

POLICY GUIDELINES

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the member's benefits, which may vary by product line. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the member's applicable benefit contract on the date the service was rendered. Services determined by HPP to be investigational or experimental, cosmetic or not medically necessary are excluded from coverage for all lines of business.

In all cases, the appropriate documentation supporting medical necessity must be kept on file and, upon request, presented to HPP.

The definition of medical necessity may vary by product due to state and federal regulatory requirements.

Clarification of the Medicare Variation for IDE and CED

1. **Investigational Device Exemption (IDE)**

   Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met.[3]

   Medicare may make payment for a Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines, prior to the submission of the first related claim, that the Medicare coverage IDE study criteria are met.[3]

   Providers participating in and seeking Medicare reimbursement for items and services in Category A or B IDE study, prior to submitting claims, are responsible for checking the CMS coverage website to identify whether CMS (or its designated entity) has approved the study for purposes of Medicare coverage.

   Effective January 1, 2015, the Medicare Advantage Organization (MAO) is responsible for payment of routine care items and services in CMS-approved Category A IDE studies.

   HPP is responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the Medicare administrative contractor (MAC) with jurisdiction over the Medicare Advantage (MA) plan's service area. HPP is responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. HPP is also responsible for CMS-approved Category B devices. HPP will not approve Category A devices because they are statutorily excluded from coverage.[1]

   A listing of all CMS-approved Category A IDE studies and Category B IDE studies will be posted on the CMS Coverage site located at http://www.cms.hhs.gov/center/coverage.asp and published in the Federal Register.[1]

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For billing requirements for items and services in FDA-approved Category A and B IDE studies, see Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 68.[3]

2. Coverage in Evidence Development (CED)

In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS-approved CED studies. HPP is responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold for that item or service has exceeded (see 42 CFR 422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development web page at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html. Billing instructions are issued for each NCD.[2]

HPP uses InterQual as our reliable, evidence-based clinical content that promotes consistent clinical decisions for appropriate, medically necessary care, services or items.

Upon request, Physicians can obtain a copy of the applicable InterQual criteria and/or HPP policies associated with our determination.

CODING

Specific codes do not apply to this policy.

BENEFIT APPLICATION

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the member's benefits which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the member's applicable benefit contract on the date the service was rendered. Services determined by HPP to be investigational or experimental, cosmetic or not medically necessary are excluded from coverage for all product lines.

DESCRIPTION OF SERVICES

Experimental and investigational services (e.g., devices, drugs, procedures, supplies, technologies, treatments) are services whose safety or efficacy is not known or are services that are used in a way that departs from generally accepted standards of practice in the medical community.

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CLINICAL EVIDENCE

N/A

DEFINITIONS

Nationally Recognized Drug Compendia: Refers to the drug compendia recognized by CMS.

Experimental Procedures and Items: Experimental procedures and items may include any procedure, study, test, drug, equipment or facility still undergoing study and which is generally not accepted as standard therapy in the medical community where alternative therapy exists. Any interpretations for specific cases must rely on and be consistent with Medicare Rules, Statutes, Federal Regulations, CMS Program Manuals, and other publications by CMS that are in place (including all CMS National Coverage Decisions) at the time the services are provided and that apply to the specific procedure and item requested.

Category A (Experimental) Devices: Refers to a device for which "absolute risk" of the device type has not been established (i.e., 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 A devices are statutorily excluded from Medicare coverage. [3]

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. [3]

Routine Care Items and Services: Refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded and there is not a national non-coverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.[3]

Pennsylvania Department of Human Services Definition of Experimental Procedure: A procedure that deviates from customary standards of medical practice, is not routinely used in the medical or surgical treatment of a specific illness or condition or is not of proven medical value.[4]

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making.

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POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Effective Date
Language was added to the "Description of Services" section to define experimental and investigational services.	B	6/1/2018
New policy.	A	8/1/2016

REFERENCES

1. Medicare Managed Care Manual, Chapter 4, Section 10.7.2 – Payment for Investigational Device Exemption (IDE) Studies at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf.

2. Medicare Managed Care Manual, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved under Coverage with Evidence at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf.)

3. Medicare Benefit Policy Manual, Chapter 14, Section 20 - Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf.

4. Definition of Experimental in the Pennsylvania Code 55 PA Code 1141.2