Clinical Policy: Experimental Technologies

Reference Number: PA.CP.MP.36
Effective Date: 09/2018
Date of Last Revision: 02/2025 Revision Log

Description
This policy outlines general guidelines to use in determining coverage of experimental or investigational, or potentially experimental or investigational medical and behavioral health technologies (i.e., drugs, procedures, devices, services, or supplies).

Note:
- These guidelines are to be used only when there is no other policy, criteria, or coverage statement available.
- For coverage of routine costs as part of a clinical trial, please refer to *PA.*CP.MP.94 Clinical Trials.

Policy/Criteria

I. It is the policy of PA Health & Wellness® (PHW) that all coverage determinations regarding technologies (i.e., drugs, procedures, devices, services, or supplies) that are or may be considered experimental or investigational must be considered on a case-by-case basis by a physician or ad hoc committee and must be made in accordance with the Benefit Plan Contract provisions and applicable state and federal requirements. The requested technology must meet both of the following:

A. A technology is requested and is considered experimental or investigational if it meets any of the following criteria:

1. It is currently the subject of active and credible evaluation (e.g., clinical trials or research) to determine:
   a. Clinical efficacy;
   b. Therapeutic value or beneficial effects on health outcomes;
   c. Benefits beyond any established medical based alternatives;
2. The most recent peer-reviewed scientific studies published or accepted for publication by nationally recognized medical journals do not conclude, or are inconclusive in findings, that the service is safe and effective for the treatment of the condition for which authorization of the service is requested;

B. Medical necessity will be evaluated on a case-by-case basis considering all of the following:

1. The technology should have final approval from appropriate governmental regulatory bodies when applicable (drugs, biological products, devices or any other product or procedures that must have final approval to market from the U.S. Food and Drug Administration (FDA) or any other governmental body with authority to regulate the technology). The indication for the technology under review does not need to be the same indication for which the technology has been approved;
2. At least two studies published in peer-reviewed medical literature should be available that would support conclusions regarding the effect of the technology and its likely net health impact;

Note:

- Such studies must, by the standards of accepted medical research, be well-designed and well-conducted investigations yielding quality and consistent results, and the results of such studies should demonstrate the effect the technology will have on the disease, injury, illness, or condition in question;
- The opinions and evaluations of national medical associations, consensus panels, and other technology evaluation bodies (e.g. Hayes), or other specialists or professionals, who are subject matter experts with respect to the technology, may be taken into consideration according to the scientific quality of the supporting evidence and rationale for such opinions and evaluations;

3. The health benefits of the technology must outweigh any harmful effects or risks to the member/enrollee;
4. Other established treatment alternatives to the technology should have been exhausted and failed or no established treatment exists;
5. The improvement to be gained by employing the technology should be attainable outside the control setting (i.e., in practice);
6. In the case of diagnostic procedures, it is anticipated that the results of the procedure will help determine the best plan of care. There must be some potential intervention or alteration to the current plan of care based on the diagnostic results;
7. The member/enrollee fully understands the risks and benefits regarding the requested technology or treatment and has given informed consent;
8. Technology is consistent with the symptoms of diagnosis of the illness or injury under treatment;
9. Technology is not furnished primarily for the convenience of the patient, the provider or supplier;
10. Technology is furnished at the most appropriate level of care that can be provided safely and effectively to the patient.

Note: The severity of the member/enrollee's condition will be considered when evaluating the request.

Background

The criteria in this policy should be weighed when evaluating the medical necessity of a technology that is or may be experimental or investigational. Where medical necessity of a technology is confirmed under this policy, steps should be taken to ensure that the technology is furnished by a participating or in-state provider to the extent possible.

Under no circumstances is this policy to be construed as an acknowledgement or acceptance by PHW of any obligation to cover experimental or investigational technologies where such technologies are not included in the benefits set forth in the Benefit Plan Contract or by applicable state and federal requirements. The Plan reserves the right to refuse coverage of an experimental or investigational technology on the grounds that such coverage is not required under the member/enrollee's benefit plan. Approval of an experimental technology with respect to a particular case does not guarantee coverage of the same technology with respect to any other cases.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Develop Pennsylvania policy, adapted from Centene Clinical policy		09/18
References reviewed	11/19	
References reviewed and revised. Added note: For clinical trials, refer to PA.CP.MP.94 Clinical Trials. Removed duplicative statement in Criteria A. regarding request for clinical trials. References reviewed and updated. Replaced all instances of member with "member/enrollee."	6/2021	
Annual review. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." References reviewed, updated and reformatted.	8/31/2022	
Annual review. Clarifying changes made to description and notes. Policy statement updated to require both of the following, A. and B. Criteria describing technology for experimental or investigational, originally under A-C, is now I.A.1 and 2. Statement "It does not have final clearance…and credible evaluation." was removed. Medical necessity for technology has been restructured and indicated under I.B.1 through 10. Removed "the technology should be used…. life-threatening condition." Added criteria points B.8.-10. Added note regarding severity of condition being considered as part of request. References reviewed and updated. Internal specialist review completed.	9/2023	
Annual review. Updated background with no clinical significance. References reviewed and updated.	03/24	04/2024
Annual review. Minor grammatical changes added to Criteria I.A.2. and Criteria I.bB.1. In Note section after Criteria I.B.2., added example of Hayes as an evaluation body. References reviewed and updated. Reviewed by internal specialist.	02/2025	

References

1. Bischel, MD. Medical review criteria guidelines for managing care. 12th edition. Apollo Managed Care Consultants. 2013.
2. Local coverage determination: Category III codes (L35490). Centers for Medicare and Medicaid Services. https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Published October 01, 2015 (revised November 17, 2024). Accessed November 18, 2024.
3. Steinberg, EP, Tunis, S, Shapiro, D. Insurance coverage for experimental technologies. *Health Aff (Millwood)*. 1995;14(4):143-158. doi:10.1377/hlthaff.14.4.143