Clinical Policy: Experimental Technologies

Reference Number: WA.CP.MP.36
Last Review Date: 04/2024 Revision Log
Effective Date: 06/01/2024

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 CP.MP.94 Clinical Trials.

Policy/Criteria
It is the policy of Coordinated Care of Washington, Inc., 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 ay 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 finding, 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, 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.
11. When the technology is not supported by any evidence regarding its safety and efficacy, medical necessity may be confirmed if
    a. The requested service or equipment has a humanitarian device exemption from the Food and Drug Administration (FDA), or,
    b. There is a local institutional review board (IRB) protocol addressing issues of efficacy and safety of the requested service that satisfies both Coordinated Care and the requesting provider.

    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 the Health Plans 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
Policy adopted. Previously WA.UM.33	07/19	07/19
References reviewed and updated. Added note regarding Clinical Trials policy. Clarified Humanitarian Use Device and Institutional Review Board exceptions.	07/20	08/20
Removed duplicative statement in Criteria A. regarding request for clinical trials. References reviewed and updated. Replaced all instances of member with "member/enrollee".	05/21	06/21
Annual review. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." References updated. Corrected logo.	03/22	03/22
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.	03/23	03/23
Annual review. Added updated background with no clinical significance. References reviewed and updated. Removed definition of Humanitarian Use Device (HUD) from section 11. a. and updated language to correspond with WAC 182-501-0165.	03/24	04/24

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 1, 2015 (revised April 27, 2023). Accessed January 9, 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
4. Washington Administrative Code (WAC) 182-501-0165 (6c). Accessed March 5, 2024.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/Enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.