

# Clinical Policy: Coverage of Experimental Technologies

Reference Number: CA.CP.MP.36

Effective Date: 09/15

Last Review Date: 12/17

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

## 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. These guidelines are to be used only when there is no other policy, criteria, or coverage statement available.

## **Policy**

It is the policy of California Health & Wellness (CH&W) 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.

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

- A. It is currently the subject of active and credible evaluation (e.g., clinical trials or research) to determine:
  - a. Clinical efficacy, *or*
  - b. Therapeutic value or beneficial effects on health outcomes, *or*
  - c. Benefits beyond any established medical based alternatives.
- B. It does not have final clearance from applicable governmental regulatory bodies (such as the US Food and Drug Administration "FDA") and unrestricted market approval for use in the treatment of a specified medical condition or the condition for which authorization of the service is requested and is the subject of an active and credible evaluation.
- C. 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.

Under no circumstances is this policy to be construed as an acknowledgement or acceptance by CH&W 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'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.

**Criteria**

The criteria listed below 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.

- A.** The technology should have final approval from appropriate governmental regulatory bodies. Regulatory bodies include 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.

If a request is for coverage of routine costs as part of a clinical trial, see CP.MP.94 Clinical Trials.

- B.** 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. 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.

- C.** The technology should be used to improve net health outcome of a severely disabling or life-threatening condition. The health benefits of the technology must outweigh any harmful effects or risks to the member.
- D.** Other established treatment alternatives to the technology should have been exhausted and failed or no established treatment exists.
- E.** The improvement to be gained by employing the technology should be attainable outside the control setting (i.e., in practice).
- F.** 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.
- G.** The member fully understands the risks and benefits regarding the requested technology or treatment and has given informed consent.

- H.** If a request, as recommended by a participating Plan provider, for treatment, services or supplies deemed experimental, is denied for a member with a terminal illness, the Plan shall provide to the member the following information within five business days of denial:
1. A statement setting forth the specific medical and scientific reasons for denying coverage.
  2. A description of alternative treatment, services, or supplies covered by the plan, if any. Compliance with this subdivision by the plan shall not be construed to mean the plan is engaging in unlawful practice of medicine.
  3. Copies of the plan’s grievance procedure or complaint form or both. The complaint form shall provide an opportunity for the member to request a conference as part of the plan’s grievance system provided under CA Health and Safety Code section 1368.

For purposes of this section terminal illness refers to an incurable or irreversible condition that has a high probability of causing death within one year or less.

Reviews, Revisions, and Approvals	Date	Approval Date
Criteria, added H. to address CA Health and Safety Code 1368.1(a)	8/12/15	
Changed reference to Centene Corporation to CH&W throughout the document. Formatting changes made throughout. Changed Centene logo to CH&W.	9/16	
Moved Important Reminders to end of document. Policy, paragraph 1, updated definition of Experimental/Investigational technologies to align with Corporate Policy.	2/23/17	
References reviewed and updated.	12/17	12/17

**References**

1. Bischel, MD. Medical review criteria guidelines for managing care. Apollo Managed Care Consultants. 12<sup>th</sup> edition, 2013.
2. Centers for Medicare and Medicaid. National coverage determination for routine costs in clinical trials (301.1). 2007 Oct 9. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA&>.
3. Centers for Medicare and Medicaid Services. Medicare Local Coverage Determination for Category III CPT Codes; (ID#L25275). Effective 9/28/09. Accessed at: [http://apps.ngsmedicare.com/lcd/LCD\\_L25275.htm](http://apps.ngsmedicare.com/lcd/LCD_L25275.htm)
4. Steinberg, EP, Tunis, S, Shapiro, D. Insurance coverage for experimental technologies. Health Affairs, 1995 Vol. 14:4.

**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

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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. This clinical policy is not intended to recommend treatment for members. Members 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 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 and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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