

Clinical Policy: Experimental Technologies

Reference Number: WNC.CP.158

Last Review Date:

Coding Implications

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Note: 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.

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 *WNC.CP.115 Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials* located at [WellCare North Carolina Providers Clinical Guidelines](#).

Policy/Criteria

- I. It is the policy of WellCare of North Carolina® 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 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 (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.*
- C. 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. Technology is consistent with the symptoms of diagnosis of the illness or injury under treatment;
 - I. Technology is not furnished primarily for the convenience of the patient, the provider or supplier;
 - J. 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 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.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original Approval date.	03/21	05/21
References updated.	02/22	05/22
Annual Review. References reviewed, updated, and reformatted.	11/22	02/23
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. NCHC verbiage removed from NC Guidance Verbiage.	05/23	05/23

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Annual Review. Coding Implications added.	05/24	05/24
Annual review. Under Description added “Notes.” In Note section after Criteria I.B.2., added example of Hayes as an evaluation body. References reviewed and updated. Under NC Guidance/Claims related information, updated state web address.		

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

North Carolina Guidance

Eligibility Requirements

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
- b. Provider(s) shall verify each Medicaid beneficiary’s eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

- a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]
Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary’s physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary’s right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state, and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information

Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

- a. Claim Type - as applicable to the service provided:
Professional (CMS-1500/837P transaction)
Institutional (UB-04/837I transaction)
Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
- c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

- d. Modifiers - Providers shall follow applicable modifier guidelines.
- e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- f. Co-payments -
For Medicaid refer to Medicaid State Plan:
<https://medicaid.ncdhhs.gov/meetingsnotices/medicaid-state-plan-public-notices>.
- g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>.

Important Reminder

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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.

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