

Corporate Medical Policy

Clinical Trial Services for Life-Threatening Conditions

Active policy, no longer scheduled for routine literature review

File Name: clinical_trial_services_for_life_threatening_conditions
Origination: 3/2002
Last CAP Review: 9/2009
Next CAP Review: NA
Last Review: 9/2009

Description of Procedure or Service

Clinical trials are scientific investigations of treatment alternatives designed to help compare the safety and efficacy of new, untested or non-standard treatments to standard currently accepted treatments. Clinical trials are intended to improve clinicians' knowledge about a treatment and to improve clinical outcomes for future patients.

Clinical trials generally proceed through four phases:

Phase I clinical trials - the study drug or treatment is given to a small group of people for the first time to evaluate its safety, determine a safe dosage range and to identify side effects;

Phase II clinical trials - the study drug or treatment is given to a large group of people to see if it is effective and to further evaluate its safety;

Phase III clinical trials - the study drug or treatment is given usually to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the drug or treatment to be used safely;

Phase IV - studies performed after the drug or treatment has been marketed to collect information about its effects in various populations and any side effects associated with long-term use.

Patients enrolled in clinical trials must be informed (if applicable) that they may be receiving standard treatment, investigational treatment, placebo treatment, or no treatment.

Based on North Carolina General Statutes § 58-3-255, **covered clinical trials** are defined as phase II, phase III, and phase IV patient research studies designed to evaluate new treatments, including prescription drugs, that 1) involve the treatment of life-threatening medical conditions, 2) are medically indicated and preferable for that patient compared to available noninvestigational treatment alternatives, and 3) have clinical and preclinical data demonstrating that the trial will likely be more effective for that patient than available noninvestigational alternatives.

Covered clinical trials must also meet the following requirements: 1) involve determinations by treating physicians, relevant scientific data, and opinions of experts in relevant medical specialties; 2) be approved by centers or cooperative groups that are funded by the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, the Agency for Health Care Research and Quality, the Department of Defense or the Department of Veterans Affairs; 3) be conducted in a setting and by personnel that maintain a high level of expertise because of their training, experience and volume of patients.

Covered clinical trial services are exempt from the medical policy criteria outlined under the

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BCBSNC Investigational (Experimental) Services medical policy.

Policy

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BCBSNC will provide coverage for Clinical Trial Services for Life-Threatening Conditions when the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

This policy will apply to all product lines of business unless otherwise indicated by the member's certificate/contract (e.g., self-funded groups).

When Clinical Trial Services for Life-Threatening Conditions are covered

BCBSNC may provide coverage for clinical trial services when all of the following criteria are met:

- A) The member, who is a potential clinical trial enrollee, has a current diagnosis with a grave prognosis (life expectancy less than 2 years):
 - 1) even if treated with currently accepted treatment options; and/or
 - 2) standard therapies have not been effective in significantly improving the condition of the member or would not be medically appropriate; and
- B) The proposed treatment is likely to be beneficial to the member based on at least two independent documents of medical and scientific evidence as defined in the Medical Term Definitions section of this policy; and
- C) The member is to be treated as part of a clinical trial satisfying **all** of the following criteria:
 - 1) The investigational drug, device, therapy or procedure is under current review by the FDA and has an Investigational New Drug (IND) number (when applicable) or is classified as an Investigational Device Exemption (IDE); and
 - 2) The clinical trial has passed independent scientific review and has also been approved by an Institutional Review Board (IRB) that will oversee the investigation; and
 - 3) The clinical trial must be a phase II, phase III, or phase IV patient research study approved by centers or cooperative groups that are funded by the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, the Agency for Health Care Research and Quality, the Department of Defense, or the Department of Veterans Affairs. (The health benefit Plan may also cover clinical trials sponsored by other entities at its sole discretion.); and
 - 4) The clinical trial must be conducted in a setting and by personnel who maintain a high level of expertise because of their training, experience, and volume of patients; and
- D) The member must:
 - 1) be enrolled in the trial; and

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- 2) provide informed consent; and
- 3) be treated according to protocol.

When Clinical Trial Services for Life-Threatening Conditions are not covered

Clinical trial services for life-threatening conditions are not covered when the criteria above are not met.

After the clinical trial ends, coverage is not provided for non-FDA approved drugs that were provided or made available to an enrollee during a covered clinical trial.

Coverage is not allowed for any clinical trial services for which the costs have been or are funded by governmental/national agencies, foundations, commercial manufacturers, distributors, charitable grants or other such research sponsors of participants' individual trials. If the service provided includes a transplant, coverage is not provided for organs sold rather than donated to a recipient.

In addition, the following clinical trial costs are not covered:

- services that are not health care services;
- services provided solely to satisfy data collection and analysis needs;
- services related to investigational drugs and devices; and
- services not provided for the direct clinical management of the patient.

In the event a claim contains charges related to covered clinical trial services but those charges have not been or cannot be separated from costs related to noncovered services, benefits will not be provided.

Policy Guidelines

Determinations of coverage are made by the Plan in accordance with North Carolina General Statutes § 58-3-255 after BCBSNC's review of available scientific data and literature, medical records, statements from attending physicians and members, and other pertinent information. Opinions of experts in a particular field and opinions and assessments of nationally recognized review organizations may also be considered by the Plan but are not determinative or conclusive.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: S9988, S9990, S9991, S9992, S9994, S9996.

See procedure code for specific procedure or service.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all

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specific information needed to make a medical necessity determination is included.

Medical Term Definitions

Informed Consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. The following facts must be included:

- Why the research is being done.
- What the researchers want to accomplish.
- What will be done during the trial and for how long.
- What risks are involved in the trial.
- What benefits can be expected from the trial.
- What other treatments are available.
- The right of the patient to ask questions or to leave the trial at any time.
- Informed consent must be documented in written form, in the language of the enrollee's choice.

Medical and Scientific Evidence is defined by BCBSNC as one of the following:

1. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
2. Peer-reviewed literature or biomedical compendia from such sources as the National Institute of Health's National Library of Medicine or The Cochrane Library.
3. An accepted indication for treatment in one of the following standard reference compendia:
 - The American Hospital Formulary Service-Drug Information,
 - The American Medical Association Drug Evaluations,
 - The American Dental Association Accepted Dental Therapeutics, and
 - The United States Pharmacopoeia Drug Information.
4. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
 - U.S. Department of Health and Human Services,
 - Federal Agency for Healthcare Research and Quality,
 - National Institutes of Health,
 - National Cancer Institute,
 - National Academy of Sciences,
 - Center for Medicare and Medicaid Services, and
 - Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

Scientific Background and Reference Sources

General Assembly of N. C., Session 2001; Session Law 2001-446; Senate Bill 199; Part III. Mandated Benefits; Subpart A. Clinical Trials; Section 3.1; Article 3 of Chapter 58 of the General Statutes § 58-3-255. *Coverage of clinical trials.*

Medical Policy Advisory Group - 2/2002

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Medical Policy Advisory Group - 3/2002

Medical Policy Advisory Group - 10/2003

Medical Policy Advisory Group - 9/2005

Centers for Medicare and Medicaid Services. National Coverage Determination for Routine Costs in Clinical Trials. Manual Section Number 310.1. Retrieved 9/20/07 from http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials

Policy Implementation/Update Information

3/02	Original Policy issued.
4/02	Medical Policy Advisory Group meeting 2/02 and 3/02. Policy revised based on medical consultant recommendations. Revised the definition for Medical and Scientific Evidence to include review from The Cochrane Library. Policy name changed from "Clinical Trial Services". Format changes. Codes added to Billing and Coding Section. Codes added to System Application Guidelines.
05/02	Processing instructions for codes S9992, S9994 and S9996 added to System Application Guidelines.
10/03	Medical Policy Advisory Group review. Information added to Billing and Coding section and Benefit Application section. No change to criteria.
11/03	Benefit Application Section corrected.
3/04	Policy Number changed from ADM9027 to MED1093.
7/29/04	Code S9988 added to Billing/Coding section of policy.
10/8/05	Specialty Matched Consultant Advisory Panel [MPAG] review on 09/08/2005. No changes to policy coverage criteria.
10/22/07	Updated Description of procedure for consistency with current NC Statute. Deleted following statement from Description, "Improvement of health outcomes for patients enrolled in clinical trials is a desirable but secondary consideration." References updated. Specialty Matched Consultant Advisory Panel review meeting 9/20/07. No changes to coverage criteria. (adn)
10/26/09	Specialty Matched Consultant Advisory Panel review 9/28/09. No change to policy statement.
6/22/10	Policy Number(s) removed (amw)
2/1/11	Policy status changed to "Active policy, no longer scheduled for routine literature review." Approved by medical director in 2010. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.