BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	**MANUAL:** MEDICAL POLICY
	REFERENCE NO.: MPO-175-0000
EFFECTIVE DATE April 1, 2014	**SUBJECT:** Clinical Trials

Blue Cross of Northeastern Pennsylvania ("BCNEPA") Medical Policy

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical policy and claims payment policy are applied. Policies are provided for informational purposes only and are developed to assist in administering plan benefits and do not constitute medical advice.

Treating providers are solely responsible for medical advice and treatment. Policies are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease.

Medical practices and information are constantly changing and BCNEPA may review and revise its medical policies periodically. Also, due to the rapid pace of changing technology and the advent of new medical procedures, BCNEPA may not have a policy to address every procedure.

In those cases, BCNEPA may review other sources of information including, but not limited to, current medical literature and other medical resources, such as Technology Evaluation Center Assessments (TEC) published by the Blue Cross Blue Shield Association. BCNEPA may also consult with health care providers possessing particular expertise in the services at issue.

DESCRIPTION:

A clinical study is a research study using human subjects to evaluate the effect of interventions or exposures on biomedical or health-related outcomes. Two types of clinical studies are interventional studies (or clinical trials) and observational studies.

A clinical trial is a study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

An observational study is a clinical study in which participants identified as belonging to study groups are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to specific interventions (as in an interventional study).

BENEFIT POLICY STATEMENT:

BCNEPA makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on product line, group or contract, therefore, Member benefits must be verified. In the event of a conflict between the Member's benefit plan document and topics addressed in Medical Policy Bulletins (i.e., specific contract exclusions), the Member's benefit plan document always supersedes the information in the Medical Policy Bulletins. BCNEPA determines medical necessity only if the benefit exists and no contract exclusions are applicable.

Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

MEDICAL POLICY STATEMENT:

BCNEPA will provide coverage for routine patient costs associated with phase(s) I, II, III, or IV clinical trials designed to prevent, detect, or treat cancer or other life-threatening diseases or conditions, including all items and services consistent with the coverage provided in the Plan that are typically covered for a qualified individual who is not enrolled in a clinical trial.

BCNEPA will not provide coverage for the following which are excluded from the definition of routine patient costs:

- The investigational item, device, or service, itself;
- Items and services that are provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient; or
- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

GUIDELINES:

Covered patient care costs include the following items and services:

- Otherwise covered physician fees, laboratory expenses, and expenses associated with a hospitalization;
- Evaluation and treatment of the patient associated with the underlying disease;
- Care costs that are consistent with the usual standards of care whenever a patient receives medical care associated with an approved cancer clinical trial; and
- Care that would be covered if such items and services were provided other than in connection with an approved cancer clinical trial.

Non-covered patient care costs include but are not limited to the following items and services:

- Costs of non-health related services that might be required for a person to receive the treatment or intervention (e.g., transportation, lodging, meals and other travel expenses)
- Costs which would not be covered under the member's contractual benefits for non-investigational treatments

An approved clinical trial means one that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition in humans that meets all of the following conditions:

1. The treatment is part of a scientific study of a new therapy or intervention which includes: specific goals; a rationale and background for the study; criteria for patient selection; specific directions for administering the therapy and monitoring patients; a definition of quantitative measures for determining treatment response; and methods of documenting and treating adverse reactions.
2. The treatment is being provided as part of a study being conducted in a Phase I, II, III or IV clinical trial.
3. The treatment is being conducted in accordance with a clinical trial approved by at least one of the following:
    - One of the National Institutes of Health
    - A National Institutes of Health cooperative group or center
    - The United States Food and Drug Administration in the form of an investigational new drug application
    - The United States Department of Defense
    - The United States Department of Veterans Affairs
    - A qualified research entity that meets the criteria established by the National Institutes of Health grant eligibility
    - A panel of qualified recognized experts in clinical research within academic health institutions in this Commonwealth
4. The proposed treatment or study has been reviewed and approved by an institutional review board of an institution in this Commonwealth.
5. The personnel providing the treatment or conducting the study are providing the treatment or conducting the study within their scope of practice, experience and training and are capable of providing the treatment because of their experience, training and volume of patients treated to maintain expertise.
6. There is no clearly superior, noninvestigational treatment alternative.
7. The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as efficacious as any noninvestigational alternative.

DEFINITIONS:

Clinical Trial Phase(s): are categorized by the Food and Drug Administration (FDA). They describe the clinical trial of a drug based on the study's characteristics, such as the objective and number of participants. There are five phases:

Phase 0: Exploratory study involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies).

Phase 1: Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.

Phase 2: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

Phase 3: Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.

Phase 4: Studies occurring after FDA has approved a drug for marketing. These include postmarket requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.

Life-threatening Condition: any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

Qualified Individual: an individual who is a participant or beneficiary in a health plan who meets the following conditions:

- The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.
- The referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate, or
- The participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate.

CODING:

- **The identification of a code in this section does not denote coverage or separate reimbursement.**
- Covered procedure codes are dependent upon meeting criteria of the policy and appropriate diagnosis code.
- The following list of codes may not be all-inclusive, and are subject to change at any time.
- Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

PROCEDURE CODES

S9988	S9990	S9991	S9992	S9994	S9996

ICD-9 DIAGNOSIS CODES

V70.7

ICD-10 DIAGNOSIS CODES
INFORMATIONAL ONLY

Z00.6

SOURCES:

BlueCare Contracts 2014.

Highmark Medical Policy Bulletin, “Coverage for Cancer Clinical Trials” (G-27), Effective Date: January 1, 2008. 1-3.

ClinicalTrials.gov U.S.National Institutes of Health [Website]: http://www.clinicaltrials.gov/. Accessed December 8, 2013

APPROVALS:

Approved by Vice President, Clinical Operations & Chief Medical Officer:

Signature:_____
(Nina M. Taggart, MA, MD, MBA)

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HISTORY:

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Policy developed by: Medical Policy Department