BlueCross BlueShield of Vermont

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Clinical Trials
Corporate Medical Policy

File Name: Clinical Trials
File Code: 10.01.VT201
Origination: 12/31/2013
Last Review: 07/2025
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Effective Date: 10/01/2025

Description/Summary

This medical policy defines the benefit responsibilities of Blue Cross VT for clinical trials, under the provisions of the Federal and State of Vermont mandates.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.
See attachment I – Coding Information & Instruction

Blue Cross VT provides benefits according to the provisions of this policy for medically necessary routine patient care costs incurred in all phases of an approved clinical trial for qualified individuals for the treatment of cancer or treatment of a life-threatening disease or condition to the same extent coverage is provided if the patient were receiving treatment outside of a clinical trial.

Definitions:

"Medically necessary care" means health care services including diagnostic testing, preventive services and aftercare appropriate, in terms of type, amount, frequency, level, setting, and duration, to the member's diagnosis or condition. Medically necessary care must be consistent with generally accepted practice parameters as recognized by health care providers in the same or similar specialty as typically treat or manage the diagnosis or condition, and

1. Help restore or maintain the member's health; **OR**
2. Prevent deterioration of or palliate the member's condition; **OR**

3. Prevent the reasonably likely onset of a health problem or detect an incipient problem

"**Routine patient care services**" means those health care services for which Blue Cross VT, subject to this regulation, is otherwise responsible under the patient's health benefit plan, including any medically necessary health care service incurred as a result of the treatment being provided to the patient for the purposes of an approved clinical trial. Routine patient care services include any physician service, diagnostic or laboratory test, hospitalization, or other service provided to the patient during the course of treatment in an approved clinical trial for a condition or one of its complications or for a complication of the treatment provided during an approved clinical trial which is consistent with the usual and customary standard of care and would be covered even if the patient were not enrolled in an approved clinical trial.

Routine patient care services <u>do not</u> include the following items:

1. The costs of investigational new drugs that have not been approved for market for any indication by the US Food and Drug Administration (FDA) or the costs of any drug being studied under an FDA-approved investigational new drug exemption for the purpose of expanding the drug's labeled indications;
2. The costs of non-health care services that may be required as a result of the treatment being provided for the purposes of the approved clinical trial;
3. The costs of services that are clearly inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis;
4. The costs of running an approved clinical trial, including collecting and analyzing data;
5. The costs associated with managing the research with the approved clinical trial;
6. Costs for non-investigational treatments and services that would not otherwise be covered under the patient's health benefit plan;
7. Any product or service paid for or supplied by a trial sponsor;
8. The investigational item, device, or service itself unless otherwise covered outside of the trial.

"Qualified Individual" means an individual who is enrolled or participating in a health plan or coverage and who is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or another life-threatening disease or condition. In general, PHS Act section 2709(a), as added by the Affordable Care Act, states that if a group health plan or health insurance issuer in the group and individual health insurance market provides coverage to a qualified individual (as defined under PHS Act section 2709(b)), then such plan or issuer: (1) may not deny the qualified individual participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (2) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in

connection with participation in the trial; and (3) may not discriminate against the individual on the basis of the individual's participation in the trial.
"Life-threatening conditions" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

"Approved clinical trial" means an organized, systematic, scientific study of therapies, tests or other clinical interventions for purposes of treatment, palliation, or prevention of life threatening diseases in human beings. An approved clinical trial must seek to answer a credible and specific medical or scientific question for the purpose of advancing care, and:

1. Is conducted by a facility and personnel capable of conducting such a trial by virtue of experience, training and volume of patients treated to maintain expertise;
2. Enrolls only those patients for whom there is no clearly superior, non- investigational treatment alternative to the clinical trial and the available clinical or preclinical data provide a reasonable expectation that the treatment obtained in the clinical trial will be at least as effective as the non-investigational alternative;
3. Is conducted only after obtaining fully informed, written consent from the patient or the patient's legally authorized representative in a manner that is consistent with current legal and ethical standards and requirements; and
4. Is conducted under the auspices of a peer-reviewed protocol that has been approved by one of the following entities:
   a. One of the National Institutes of Health (NIH); or
   b. An NIH-affiliated cooperative group that is a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group; or
   c. The FDA in the form of an investigational new drug application or exemption; or
   d. The federal departments of Veterans Affairs or Defense; or
   e. The Center for Disease Control and Prevention; or
   f. The Agency for Health Care Research and Quality; or
   g. The Centers for Medicare & Medicaid Services.
5. The individual must be eligible to participate in an approved clinical trial according to the trial protocol.

Guidance

Blue Cross VT will provide benefits under the provisions in this policy, only when the providers in the clinical trial are participating providers.

Reference Resources

1. The Federal Clinical Trial Mandate. 42. U.S.C.A.300gg-8.
2. State of Vermont. Health Insurance Coverage for Cancer Clinical Trials. Regulation H-2005-03.
3. Vermont Statutes Online. Title 8: Banking and Insurance. Chapter 107: Health

Insurance. 8 V.S.A. 4088b.

4. Vermont Statutes Online. Title 8: Banking and Insurance. Chapter 107: Health Insurance. 8 V.S.A. 4088c.
5. Vermont Statutes Online. Title 8: Banking and Insurance. Chapter 107: Health Insurance. 8 V.S.A. 4100e.

Document Precedence

Blue Cross and Blue Shield of Vermont (Blue Cross VT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, Blue Cross VT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

Blue Cross VT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, Blue Cross VT reserves the right to recoup all non- compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Benefits are subject to all terms, limitations, and conditions of the subscriber contract.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

01/2014	This policy is needed in response to the Federal Clinical Trial Mandate.
6/9/2015	Updated list of patient care services which are not considered routine for clinical trials. Prior approval requirement removed.
05/2016	Grammatical edits only. No other changes. Review date updated.
03/2017	Reviewed, policy statement remains unchanged.
03/2018	Reviewed, policy statement remains unchanged.
05/2019	Reviewed, policy statement remains unchanged.
06/2021	Reviewed, policy statement remains unchanged.
06/2022	Reviewed, Policy statement remains unchanged.
06/2023	Reviewed, policy statement remains unchanged.
07/2024	Policy reviewed. References reviewed. No change to policy statement.
07/2025	Policy reviewed. Reference updated. No change to policy statement.

Eligible Providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by Blue Cross VT Medical Directors

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Vice President & Chief Medical Officer

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Senior Medical Director

Attachment I
Coding information & Instruction

Code Type	Number	Description	Policy Instructions
Apply the following CPT modifiers to claims when applicable.			
HCPCS Modifier	-Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study	
HCPCS Modifier	-Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study	
Clinical Trial specific diagnosis (primary or secondary position)			
ICD-10- CM	Z00.6	Encounter for examination for normal comparison and control in clinical research program	
The following codes will be denied as benefit exclusions			
HCPCS	S9992	Transport costs for clinical trial	
HCPCS	S9994	Lodging costs for clinical trial	
HCPCS	S9996	Meals for clinical trial	
HCPCS	S9999	Sales Tax	