



An Independent Licensee of the Blue Cross and Blue Shield Association.

## Off-Label Drug Corporate Medical Policy

File Name: Off-Label Drug  
File Code: UM.PHARM.01  
Origination: 08/2016  
Last Review: 01/2021  
Next Review: 01/2022  
Effective Date: 02/01/2021

### Description/Summary

This Policy provides assistance in interpreting Blue Cross Blue Shield of Vermont's Prescription and Medical Benefit for deciding drug coverage.

### Definitions

Chronic Care: health services provided by a health care professional for an established clinical condition that is expected to last a year or more and that requires ongoing clinical management attempting to restore the individual to highest function, minimize the negative effects of the condition and prevent complications related to chronic conditions. Examples of chronic conditions include anxiety disorder, asthma, bipolar disorder, COPD, diabetes, heart disease, major depression, post-traumatic stress disorder, schizophrenia or substance abuse.

Compendia: a comprehensive listing of FDA approved drugs and biologicals (CMS.org)

Prescription Drug and Biologics: are prescribed by a provider for a medical condition; FDA-approved; and approved by us for reimbursement for the specific medical condition being treated or diagnosed, or as otherwise required by law

Medically Necessary Care: Health care services including diagnostic testing, preventive services and after-care appropriate, in terms of type, amount, frequency, level, setting and duration to the member's diagnosis or condition. Medically Necessary Care must be informed by generally accepted medical or scientific evidence and consistent with generally accepted practice parameters as recognized by health care Providers in the same or similar general specialty as typically treat or manage the diagnosis or condition, and:

Help restore or maintain the member's health OR prevent deterioration of or palliate the member's condition OR prevent the reasonably likely onset of a health problem or detect a

developing problem (Vermont Rule 9-03)

Off Label Use of a Drug: use of a drug for other than the particular condition for which the Federal Drug Administration gave approval.

Orphan Drug Status: The Orphan Drug Act provides granting specific status to a drug or biological product to treat a specific rare disease or condition (fda.gov).

Serious Condition: A disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment based on its impact on such factors as survival, day-to-day functioning or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>)

## Policy Guidelines

- A. If a prescription drug or biologic has been designated orphan drug status, this policy does not apply. The request may be approved on the FDA orphan drug designation status. Designation status may be found in DRUGDEX system by Micromedex or by going to fda.gov and search orphan drug designations and approvals. <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm>
- B. Off Label prescription drug use for oncologic indications. BCBSVT follows Vermont State Statute. See: <http://legislature.vermont.gov/statutes/section/08/107/04100e>
- C. In the absence of prior authorization clinical criteria that address the specific off-label use, off-label prescription drug use for non-oncologic indications may be considered **medically necessary** when **ALL** of the following conditions are met:
  1. The requested drug is approved by the U.S. Food and Drug Administration; **AND**
  2. The requested drug is for an indication, population, dose, dosing frequency, or treatment duration other than what was approved by the U.S. Food and Drug Administration; **AND**
  3. The requested drug is prescribed by a licensed, registered health care professional authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice; **AND**
  4. The requested drug is intended to treat a chronic and/or serious condition (as defined above); **AND**
  5. There is documented history of failure, contraindication, or intolerance to standard, conventional therapies to treat or manage the disease or condition, where available; **AND**
  6. The conditions of the request (diagnosis, dose, dosing frequency, duration of

treatment, and population) are clinically supported by **at least ONE** of the following:

- i. Facts & Comparisons eAnswers<sup>®</sup> under the Off Label Uses section with a Level of Evidence Scale of A or B **OR** Dosage Section
  - ii. DRUGDEX System by Micromedex has a Strength of Recommendation rating of Class I OR Class IIa under the Therapeutic Uses Section
- D. If the criteria in A **OR** B **OR** C above are not met, the drug and its requested use are considered **investigational**.

### Reference Resources

1. U.S. Food and Drug Administration Regulatory Information: “Off-Label” and Investigational Use of Marketed Drugs, Biologics, and Medical Devices - Information Sheet. <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm>. Last updated 05/06/2020. Accessed 11/2020.
2. United Healthcare<sup>®</sup> Drug Policy. Copyright 2015 United Healthcare<sup>®</sup>
3. Facts & Comparisons eAnswers<sup>®</sup>. <https://fco.factsandcomparisons.com/lco/action/home>. Accessed: 11/2020.
4. 42CFR 414.930. Available at: <https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol3/pdf/CFR-2011-title42-vol3-sec414-930.pdf>. Accessed 11/2020.

### Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) 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, BCBSVT 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

BCBSVT 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, BCBSVT 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

08/2016	New Policy
12/2016	Changes to reflect medical policy to align with certificate language.
02/2017	Revised to add orphan drug designation status.
04/2017	Revised to include a statement when the off label criteria are met and the drug is considered medically necessary.
07/2018	Reviewed policy and removed AHFS (American Hospital Formulary Service) Drug Information book as a valid compendium. Updated references. No changes to policy statements.
7/2019	Annual review. Tightened strength of recommendation/level of evidence accepted by removal of IIb (Micromedex) and G (eAnswers®).
11/2020	Policy reviewed. Policy Guideline C.2. added to clarify what constitutes off-label. Policy Guidelines reformatted.
01/2021	Minor policy update under Description/Summary to reflect this policy addresses Prescription and Medical Benefit.

Health Care Procedure Coding System (HCPCS) codes related to chemotherapy drugs, drugs administered other than oral method, and enteral/parenteral formulas may be subject to National Drug Code (NDC) processing and pricing. The use of NDC on medical claims helps facilitate more accurate payment and better management of drug costs based on what was dispensed and may be required for payment. For more information on BCBSVT requirements for billing of NDC please refer to the provider portal

<http://www.bcbsvt.com/provider-home> latest news and communications.

### Eligible providers

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

### Approved by BCBSVT Medical Directors

### Date Approved

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