Sentara Health Plans

Commercial

Off-Label Drug Use, Pharmacy 12

Table of Content

Effective Date	10/2008
Next Review Date	12/2025
Coverage Policy	Pharmacy 12
Version	5

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses Off-Label Drug Use.

Description & Definitions:

Off-Label drug use describes using medication that is approved by the Food and Drug Administration for something that is otherwise not intended per the drug label and/or drug insert.

Criteria:

Off-label drug use and off-label dosing are considered medically necessary for **one or more of the following**:

- **Initial therapy authorization** when **all of the following** are met:
  - The member has a documented history of failure, intolerance, or contraindication to standard, conventional therapies meeting the following:
    - Approved and labeled by the FDA for the treatment of the member's diagnosis
    - Having strong support for use in the requested condition per clinical guidelines
  - The drug is currently approved by the United States Food and Drug Administration (FDA) for another indication
  - The drug is being prescribed to treat a medical condition that is not listed in the product's label and for which medical treatment is medically necessary
  - Approval has been obtained by a Sentara Health Plan Medical Director or Pharmacist
  - A drug will be considered as being used for an off-label indication when it meets one of the following:
    a) The use of the drug for the ordered indication is listed in one the following compendia:
       - American Hospital Formulary Service Drug Information® (AHFS®)
       - American Society of Health-System Pharmacists Drug Information [AHFS Drug Information]
       - Clinical Pharmacology (Elsevier/Gold Standard, Inc.)
       - Lexi-Drugs (Wolters Kluwer)

- Merative Micromedex ®with all of the following: Evidence favors efficacy; Strength of Recommendation Class I, or IIa, or IIb; Strength of Evidence Category A or B;
- National Comprehensive Cancer Network® (NCCN®) Drug & Biologics Compendium ® Category of Evidence and Consensus 1 or 2A [*insert reference link to chemotherapy policy*]

OR

b) Two or more adequate and well-controlled studies (preferably at different institutions) performed by experts qualified by scientific training and experience can be identified using the drug for the ordered indication, appropriate dose, and dosing frequency. This excludes case reports, letters, posters, and abstracts.

- **Continuation of therapy authorization** when **all of the following** are met:
  - All indication-specific and dosing conditions outlined above must be met
  - The member is not experiencing unacceptable toxicity to the requested drug
  - The member has been observed to have a positive clinical response since the beginning of therapy evidenced by disease stability, or mild progression

Off label drug use is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- The member has failed a previous course or trial of the requested drug
- The member is currently part of a clinical trial utilizing this medication

Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2024: October – Added criteria relating to the member's need for off-label drug utilization, updated description of service and criteria. Added criteria for continued use.
- 2020: December
- 2019: November
- 2014: November
- 2013: October
- 2012: November
- 2011: March

Reviewed Dates:

- 2023: October
- 2022: October
- 2021: December
- 2019: February
- 2018: February
- 2017: January
- 2015: September

- 2010: December
- 2009: November

Effective Date:

- November 2008

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

Code of Federal Regulations. Title 42, Chapter IV, Subchapter B, Part 414, Subpart K. § 414.930 Compendia for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen. 9.12.2024. Retrieved 9.16.24. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-K/section-414.930

U.S. Food and Drug Administration. Understanding Unapproved Use of Approved Drugs "Off Label". 2.5.2018. Retrieved 9.16.2024. https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label

Hayes. A symplr Company. Retrieved 9.16.24. https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522off%2520label%2520drug%2520use%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%2522:%255B%2522*%2522%255D,%2522sorts%2522:%255B%257B%2522field%2522:%2522_score%2522,%2522direction%2522:%2522desc%2522%257D%255D,%2522filters%2522:%255B%255D%257D

Centers for Medicare and Medicaid Services. CMS.gov. Non-Local LCD. Drugs and Biologicals, Coverage of, for Label and Off-Label Uses. L33394. 8.1.2024. Retrieved 9.16.24. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33394&ver=50&

MCG. Informed Care Strategies. 28th Edition. Retrieved 6.18.24. https://careweb.careguidelines.com/ed28/index.html

COMMONWEALTH OF VIRGINIA. DEPARTMENT OF MEDICAL ASSISTANCE SERVICES. CardinalCare Virginia's Medicaid Program. Cardinal Care Managed Care Contract. July 1, 2024 – June 30, 2025. Retrieved 9.18.2024. https://www.dmas.virginia.gov/media/cyod1lnw/cardinal-care-managed-care-fy2025-contract.pdf

National Comprehensive Cancer Network. NCCN Recognition Program. 2024. Retrieved 9.18.24. https://www.nccn.org/compendia-templates/compendia/recognition-program

Carelon. Clinical Guidelines. Retrieved 9.18.2024. https://guidelines.carelonmedicalbenefitsmanagement.com/?s=off+label&et_pb_searchform_submit=et_search_process&et_pb_search_cat=11%2C1%2C96&et_pb_include_posts=yes

American Family Physician Association. Off-Label Use of Prescription Drugs. 8.1.2023. Retrieved 9.18.24. https://www.aafp.org/pubs/afp/issues/2003/0801/p425.html

Agency for Healthcare Research and Quality. Understanding Unapproved Use of Approved Drugs "Off Label"2.5.2018.Retreived 9.18.24. https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label

CHAPTER 656: An Act to amend and reenact § 2.1-20.1, as it is currently effective and as it may become effective, and § 38.2-3407.5 of the Code of Virginia, relating to off-label drug use. [S 1164] Approved March 21, 1997. Retrieved 9.18.2024. https://lis.virginia.gov/cgi-bin/legp604.exe?971+sum+SB1164

Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

MUST SEE MEMBER BENEFIT FOR DETERMINATION.
We only cover DME that is Medically Necessary and prescribed by an appropriate Provider. We also cover colostomy, ileostomy, and tracheostomy supplies, and suction and urinary catheters. We do not cover DME used primarily for the comfort and wellbeing of a Member. We will not cover DME if We deem it useful, but not absolutely necessary for Your care. We will not cover DME if there are similar items available at a lower cost that will provide essentially the same results as the more expensive items.

Pre-Authorization is Required for All Rental Items.

Pre-Authorization is Required for All Repair and Replacement.

Keywords:

SHP Off-Label Drug Use, SHP Pharmacy 12, Food and Drug Administration, FDA