# Off-Label Drug Use

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|---|---|
| Effective Date | 10/2008 |
| Next Review Date | 10/2024 |
| Coverage Policy | Pharmacy 12 |
| Version | 4 |

**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 **All** of the following:

- Sentara Health Plan Pharmacist or Sentara Health Plan Medical Director approval obtained
- 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
- The prescribed drug use or dosing regimen is supported by **1 of more** of the following:
  - American Hospital Formulary Service Drug Information® (AHFS®)
  - American Society of Health-System Pharmacists Drug Information [AHFS Drug Information]
  - Micromedex DrugDex System [DrugDex]
  - Clinical Pharmacology (Elsevier/Gold Standard, Inc.)
  - Lexi-Drugs (Wolters Kluwer)
  - Truven Health Analytics Inc., DrugPoints® with **all of the** following:
    - Strength of Recommendation Class I or IIa
    - Strength of Evidence Category A or B
    - Efficacy Class I or IIa
  - National Comprehensive Cancer Network® (NCCN®) Drug & Biologics Compendium ® Category of Evidence and Consensus 1 or 2A
  - Two articles from major scientific or medical peer-reviewed journals (excluding case reports, letters, posters, and abstracts), or published studies having validated and uncontested data, which support

the proposed use for the specific medical condition as safe and effective using **1 or more** of the following:

- ▪ Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet.
- ▪ Accepted study designs include, but are not limited to, randomized, double blind, placebo controlled clinical trials.

Off-label drug use is considered **not medically necessary** for any use other than those indicated in clinical criteria.

## 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:
- 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).

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Off-Label Medication: From a Simple Concept to Complex Practical Aspects. (2021, Oct). Retrieved Sept 21, 2023, from International Journal Environmental Research and Public Health: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8508135/

Off-Label Use of Prescription Drugs. (2021, Feb 23). Retrieved Sep 21, 2023, from Congressional Research Service: https://sgp.fas.org/crs/misc/R45792.pdf

## 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