Sentara Health Plans

Medicaid

Off-Label Drug Use

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Effective Date	10/2008
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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

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

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).

"Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices. (2020, May 6). Retrieved Sept 21, 2023, from FDA: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices

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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: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

All medically necessary medical equipment and supplies under the Virginia Administrative Code (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner. Only supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual; • Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

Keywords:

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