Sentara Health Plans

Medicaid

Off-Label Drug Use, Pharmacy 12

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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.

Children must be reviewed in accordance with EPSDT requirements to cover medically necessary drugs based upon a case-by-case review of the individual child's needs to authorization requirements.

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

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).

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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: *

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