



## Administrative Policy Statement TRICARE

Policy Name		Policy Number	Date Effective
Medical Necessity – Off Label		PAD-0061-TRICARE	01/01/2026
Policy Type			
Medical	ADMINISTRATIVE	Pharmacy	Reimbursement

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## A. Subject

### Pharmacy – Off Label

## B. Background

The U.S. Food and Drug Administration (FDA) approves drugs for specific indications included in the drug's product information label. Off-label or "unlabeled" drug use is the utilization of an FDA approved drug for uses other than those listed in the FDA approved labeling or in treatment regimens or populations that are not included in approved labeling. Many off-label uses are effective, well documented in the peer-reviewed literature, and widely used even though the manufacturer has not pursued the additional indications.

The FDA advises physician's use of off-label or "unlabeled" drugs must be done in a well-informed manner in conjunction with firm scientific rationale and medical evidence. TRICARE Prime® Demo by CareSource Military & Veterans™ will employ, at its discretion, drug utilization management programs (i.e., prior authorization) to ensure appropriate and safe use of medications.

**NOTE:** *The Introduction section is for your general knowledge and is not to be construed as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals and is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider can also be a place where medical care is given, like a hospital, clinic or lab. This policy informs providers about when a service may be covered.*

- **Multi-ingredient Compound** – a product containing two or more ingredients that is not FDA approved and is prepared upon the order of a physician for a patient.

## C. Definitions

- **FDA Approved medication:** Is the official description of a drug product which includes indication; who should take it; adverse events; instructions for uses in pregnancy; children, and other populations; and safety information for the patient. Labels are often found inside drug product packaging.
- **Off-label or "unlabeled" drug use:** Is the use of a drug approved by the U.S. Food and Drug Administration (FDA) for other uses that are not included in approved labeling. The FDA approves drugs for specific indications that are included in the drug's labeling. When a drug is used for an indication other than those specifically included in the labeling, it is referred to as an off-label use. Many off-label uses are effective, well documented in the literature, and widely used.

## D. Policy

TRICARE Prime® Demo by CareSource Military & Veterans™ will review prior authorization requests for coverage based on medical necessity. This policy will not supersede drug-specific criteria



developed and approved by the TRICARE Prime® Demo by CareSource Military & Veterans™ Pharmacy and therapeutics Committee (P&T).

Requests for off-label uses of a drug will be considered for approval according to the following criteria:

- I. Documentation must be submitted showing the member has tried and failed the existing FDA approved and/or clinical guideline recommended therapies unless contraindicated or not tolerated; AND
- II. The prescribed use must be supported by one or more of the following:
  - a. Narrative information from American Hospital Formulary Service Drug Information (AHFS) or Clinical Pharmacology
  - b. Lexicomp: Evidence level A
  - c. Micromedex: Recommendation class I, IIa, or IIb
  - d. Evidence from at least two published studies from major scientific or medical peer reviewed journals demonstrates safety and efficacy for the specified condition in a comparable population (i.e., age group, level of disease severity, etc.)  
*If applicable clinical trial is yet to be published but interim results are supportive, this may be taken into consideration by the clinician reviewer.*
- III. Requests for members less than 21 years old are reviewed for coverage for Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) on a case-by-case basis in addition to the criteria above.

**NOTE:** For off-label use of oncology drugs, please refer to the policy titled “Oncology Regimens” accessible from the TRICARE Prime® Demo by CareSource Military & Veterans™ website.

For Reauthorization:

- I. Documentation has been provided showing the member has had a positive response to therapy; AND
- II. Documentation has been provided showing the member is compliant with therapy.

## E. Conditions of Coverage

### AUTHORIZATION PERIOD

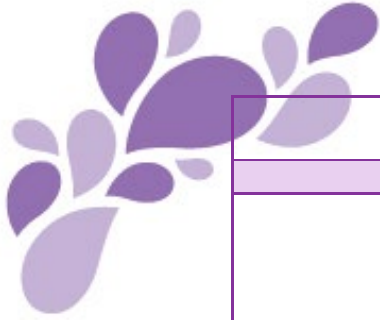
Approved authorizations are designated an appropriate authorization period. Continued treatment may be considered when the member has shown tolerability and a positive clinical response.

## F. Related Policies/Rules

Oncology Regimens

## G. Review/Revision History

DATES		ACTION
Date Issued	06/06/2013	
Date Revised	10/30/2014	Added definition to excluded indications
	05/05/2015	Removed indications in reference of plan specific member handbooks, EOC, etc. Removed specialty and subspecialty associations and combined with no determinations policy



	<b>12/15/2015</b>	Revised class/category and defined evidence criteria for article submissions
	<b>01/11/2018</b>	Updated format
	<b>02/12/2021</b>	Updated format, copied to new template. General edits for clarity. Added note about clinical trials in progress. Removed content related to orphan drugs and compassionate use. Removed cancer drug section and refer to separate policy. Added component that member must try and fail available FDA approved on label drugs first. Amended list of acceptable compendia to include Lexicomp. Updated reference section.
	<b>11/02/2022</b>	Updated the title of the oncology policy that is referenced. No other changes.
	<b>2/24/2023</b>	Added note on EPSDT.
	<b>5/21/2024</b>	Annual review, no updates.
	<b>5/22/2025</b>	Added reauth criteria.
<b>Date Effective</b>	<b>1/1/2026</b>	
<b>Date Archived</b>		

#### H. References

N/A

The Administrative Policy Statement detailed above has received due consideration as defined in the Administrative Policy Statement Policy and is approved.