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## **PRESCRIPTION MEDICATIONS FOR THE TREATMENT OF CANCER**

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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### **Description:**

Arizona Revised Statutes §20-826 (R), 20-1057 (V) and 20-2326 require coverage for the off-label use of a prescription drug for the treatment of cancer and medically necessary services directly associated with the physical/actual administration of the drug even if the FDA has not approved that drug for that specific type of cancer.

For the purpose of this guideline, an off-label prescription drug is a drug meeting all the requirements set forth in Arizona law, which is prescribed by a physician for the treatment of cancer but which is not FDA-approved for that specific type of cancer.



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**MEDICAL COVERAGE GUIDELINES  
SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE: 12/20/10  
LAST REVIEW DATE: 09/16/14  
LAST CRITERIA REVISION DATE: 09/04/12  
ARCHIVE DATE:**

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## **PRESCRIPTION MEDICATIONS FOR THE TREATMENT OF CANCER (cont.)**

### **Criteria:**

**All requests for the off-label use of an FDA-approved prescription drug prescribed for the treatment of cancer will be reviewed by the medical director(s) and/or clinical pharmacist.**

- The off-label use of an FDA-approved prescription drug prescribed for the treatment of cancer and medically necessary services directly associated with the physical/actual administration of that prescription drug are **eligible for coverage** under applicable Arizona Revised Statutes if **ALL** of the following are met:
  1. The drug must be prescribed by a licensed physician and dispensed by a licensed pharmacist
  2. The drug is FDA-approved for some indication with no FDA contraindication for treatment of the specific type of cancer
  3. The drug is recognized as safe and effective for treatment of the specific type of cancer as referenced in **ANY** of the following:
    - The American Hospital Formulary Service Drug Information, a publication of the American Society of Health System Pharmacists
    - The National Comprehensive Cancer Network Drugs and Biologics Compendium
    - Thomson Micromedex Compendium Drugex; Elsevier Gold Standard's Clinical Pharmacology Compendium
    - Other authoritative compendia as identified by the Secretary of the U.S. Department of Health and Human Services
    - **ALL** of the following:
      - At least two articles from major peer reviewed professional medical journals have recognized, based on scientific or medical criteria, the drug's safety and effectiveness for treatment of the indication for which the drug has been prescribed
      - No article from a major peer reviewed professional medical journal has concluded, based on scientific or medical criteria, that the drug is unsafe or ineffective or that the drug's safety and effectiveness cannot be determined for the treatment of the indication for which the drug has been prescribed
      - The literature meets the uniform requirements for manuscripts submitted to biomedical journals established by the international committee of medical journal editors or is published in a journal specified by the United States department of health and human services as acceptable peer reviewed medical literature pursuant to section 186(t)(2)(B) of the Social Security Act (42 United States Code section 1395x(t)(2)(B))
- Benefits are not available for services or treatments otherwise not eligible for coverage under the member's specific benefit plan.



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## **PRESCRIPTION MEDICATIONS FOR THE TREATMENT OF CANCER (cont.)**

### **Resources:**

1. State of Arizona. Drugs; cancer treatment; definitions. *Arizona Revised Statutes 20-2326*.
2. State of Arizona. Subscription contracts; definitions. *Arizona Revised Statutes 20-826 (R)*.
3. State of Arizona. Evidence of coverage by health care services organizations; renewability; definitions. *Arizona Revised Statutes 20-1057 (V)*.
4. Blue Cross Blue Shield of Arizona. Benefit Plan Booklet.