BlueCross BlueShield Arizona

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| **PHARMACY COVERAGE GUIDELINES** | |
| **SECTION: DRUGS** | |
| **ORIGINAL EFFECTIVE DATE:** | **3/15/2018** |
| **LAST REVIEW DATE:** | **5/20/2021** |
| **LAST CRITERIA REVISION DATE:** | **5/20/2021** |
| **ARCHIVE DATE:** | |

# ERLEADA™ (apalutamide)

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

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**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.**

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

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



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

# ERLEADA™ (apalutamide)

**Criteria**:

- **Criteria for initial therapy:** Erleada (apalutamide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist or Urologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of prostate cancer and used as **ONE** of the following:
     a. Systemic therapy in combination with androgen deprivation therapy (after orchiectomy or with LHRH agonist or degarelix) for castration-naïve M1 disease

     b. Secondary hormone therapy for non-metastatic (M0) castration-resistant disease and PSA doubling time (PSADT) of ≤ 10 months in a patient with no or minimal symptoms with continuation of androgen deprivation therapy to maintain castrate levels of serum testosterone (less than 50 ng/dL)

     c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. Individual has a baseline Eastern Cooperative Oncology Group Performance Status (ECOG) of 0-1

  **Initial approval duration**: 6 months

- **Criteria for continuation of coverage (renewal request):** Erleada (apalutamide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist or Urologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as:
        i. No evidence of disease progression
           - Evidence of disease progression seen as
             a. Appearance of first distant metastasis defined as new bone or soft tissue lesion
             b. Enlarging lymph node above iliac bifurcation
           - Initiation of new treatment
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued us

  3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Seizure
        ii. Cerebrovascular event
        iii. Ischemic cardiovascular event

5. There are no significant interacting drugs

**Renewal duration**: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-Cancer Medications**

2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

**Description:**

Erleada (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer and for patients with metastatic castration-sensitive prostate cancer. Patients should also use of a gonadotropin-releasing hormone (GnRH) analog (also known as luteinizing hormone releasing hormone (LHRH) agonist or analog) **or** should have had bilateral orchiectomy.

Patients who do not achieve adequate suppression of serum testosterone (< 50 ng/dL) with medical or surgical castration can be considered for additional hormonal manipulations.

In the setting in which patients have no or minimal symptoms, administration of secondary hormonal therapy including addition of, or switching to, a different antiandrogen, addition of adrenal/paracrine androgen synthesis inhibitors, or use of an estrogen can be considered.

**Definitions:**

**Castration-resistant prostate cancer (CRPC):**
CRPC demonstrated during continuous ADT, defined as 3 PSA rises, at least 1 week apart, with the last PSA greater than (>) 2 nanogram per milliliter (ng/mL)

**Prostate Specific Antigen Doubling Time (PSADT:**
PSADT is calculated by using at least three prostate-specific antigen (PSA) values obtained during continuous ADT (androgen deprivation therapy)

## ERLEADA™ (apalutamide)

**Staging System for Prostate Cancer, excerpts:**

No – No positive regional nodes

N1 – Metastases in regional lymph node(s)

M0 – No distant metastasis
M1 – Distant metastasis
- M1a: Non-regional lymph node(s)
- M1b: Bone(s)
- M1c: Other site(s) with or without bone disease
- [Note: When more than one site of metastasis is present, the most advanced category is used – M1c

**Gonadotropin-releasing hormone (GnRH) analogs or agonists: (**Also referred to as luteinizing hormone releasing hormone (LHRH) agonists or analogs)

Zoladex (goserelin acetate) subcutaneous implant
Vantas (histrelin acetate) subcutaneous implant
Eligard (leuroplide acetate) subcutaneous injection
Lupron Depot (leuprolide acetate) intramuscular injection
Trelstar (triptorelin pamoate) intramuscular injection

**Gonadotropin-releasing hormone antagonist:**

Firmagon (dagarelix) subcutaneous injection
Orgovyx (relugolix)

**Antiandrogens, oral:** to maintain castrate serum levels of testosterone (< 50 ng/dL)

Zytiga (abiraterone acetate)
Erleada (apalutamide)
Casodex (bicalutamide)
Nubequa (darolutamide)
Xtandi (enzalutamide)
Flutamide
Nilandron (nilutamide)

## ERLEADA™ (apalutamide)

**Resources:**

Erleada (apalutamide) product information, revised by Janssen Products, LP. 11-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on March 16, 2021.

Dawson NA. Overview of the treatment of disseminated castration-sensitive prostate cancer. In: UpToDate, Vogelzang N, Lee WR, Richie JR, Savarese DMF (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on March 15, 2021.

Dawson NA. Overview of the treatment of castration-resistant prostate cancer (CRPC). In: UpToDate, Vogelzang N, Lee WR, Richie JR, Savarese DMF (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on March 15, 2021.

Lee RJ, Smith MR. Initial systemic therapy for castration-sensitive prostate cancer. In: UpToDate, Vogelzang N, Lee WR, Richie JR, Savarese DMF (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on March 15, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer Version 2.2021 – Updated February 17, 2021. Available at https://www.nccn.org. Accessed on March 16, 2021.

National Comprehensive Cancer Network (NCCN) Compendium: Erleada. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021(c); Available at: http://www.nccn.org. Accessed on March 16, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.