BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/15/18**
SECTION: DRUGS	**LAST REVIEW DATE: 5/17/18**
	LAST CRITERIA REVISION DATE: 5/17/18
	ARCHIVE DATE:

ERLEADA™ (apalutamide) oral tablet

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) oral tablet (cont.)

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 an Oncologist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of non-metastatic castration-resistant prostate cancer (NM-CRPC)
  4. Individual to continue use of a gonadotropin-releasing hormone (GnRH) analog **unless** has had bilateral orchiectomy
  5. Serum testosterone level is < 50 ng/dL
  6. Imaging studies show no metastases
  7. If PSA doubling time > 10 months, individual has failure, contraindication or intolerance to **two** the following preferred step therapy agents:
     - Bicalutamide
     - Flutamide
     - Nilutamide

  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 an Oncologist
  2. Individual's condition has not worsened while on therapy
     - Worsening is defined as:
       - Evidence of disease progression seen as
         - Appearance of first distant metastasis defined as new bone or soft tissue lesion
         - Enlarging lymph node above iliac bifurcation
       - Initiation of new treatment
  3. Individual has been adherent with the medication
  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Significant adverse effect such as:
       - Seizure

ERLEADA™ (apalutamide) oral tablet (cont.)

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Erleada (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.

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.

National Comprehensive Cancer Network (NCCN):
Clinical Practice Guidelines in Oncology: Prostate Cancer, v 2.2018, March 8, 2018
Principles of ADT

- ADT for M0 or M1 castration-naïve disease:
  - Orchiectomy
  - LHRH agonist alone (need 1st generation antiandrogen for ≥ 7 days to prevent testosterone flare if metastases are present in weight bearing bones
    - Goserelin, histrelin, leuprolide, or triptorelin
    -
  - LHRH agonist plus 1 generation antiandrogen
    - Nilutamide, flutamide, or bicalutamide
  - LHRH antagonist
    - Degarlix
  - Orchiectomy, LHRH agonist, or LHRH antagonist plus abiraterone plus prednisone (for M1)

- Secondary hormone therapy for M0 or M1 castration resistant prostate cancer:
  - Continue LHRH agonist or antagonist to maintain castrate serum levels of testosterone (< 50 ng/dL)
    - AND ADD any of the following:
      - 2nd generation antiandrogen
        - Apalutamide (for M0 & PSADT ≤ 10 months)
        - Enzalutamide (for M1)
      - Androgen metabolism inhibitor (for M1)
        - Abiraterone plus prednisone
      - 1st generation antiandrogen
        - Nilutamide, flutamide, or bicalutamide
      - Ketoconazole, unless disease progressed on abiraterone with prednisone
      - Ketoconazole plus hydrocortisone, unless disease progressed on abiraterone with prednisone
      - Corticosteroids

ERLEADA™ (apalutamide) oral tablet (cont.)

- DES or other estrogen

Definitions:

Antiandrogens, oral:
- Zytiga (abiraterone acetate)
- Erleada (apalutamide)
- Bicalutamide
- Xtandi (enzalutamide)
- Flutamide
- Nilutamide

Gonadotropin-releasing hormone (GnRH) agonists: also referred to as luteinizing hormone releasing hormone (LHRH) agonists or analogues:
- 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

Resources:

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.

Erleada. Package Insert. Revised by manufacturer 02/2018. Accessed 2-16-18.

Erleada product information accessed 05-11-18 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d1cda4f7-cb33-46ea-b9ac-431f6452b1a5

NCCN Clinical Practice Guidelines in Oncology: Prostate cancer. Version 1.2018, Feb 14, 2018.
https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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