



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/15/18
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE: 5/16/19
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.

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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 **ONE** of the following:
 - Non-metastatic (M0) castration-resistant prostate cancer (CRPC) used as secondary hormone therapy in a patient with no or minimal symptoms that has a PSA doubling time (PSADT) of \leq 10 months
 - 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 continue use of a gonadotropin-releasing hormone (GnRH) analog (also known as luteinizing hormone releasing hormone (LHRH) agonist or analog, see Definitions section) **unless** has had bilateral orchiectomy
 5. Serum testosterone level is $<$ 50 ng/dL
 6. Imaging studies show no metastases

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:

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- Seizure

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 1.2019, March 6, 2019

Principles of ADT

- 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)
 - For patient with no or minimal symptoms AND ADD any of the following secondary hormonal therapies for M0 or M1:
 - 2nd generation antiandrogen
 - Apalutamide (for M0 & PSADT ≤ 10 months)
 - Enzalutamide (for M0 PSADT ≤ 10 months or M1)
 - Androgen metabolism inhibitor (for M1)
 - Abiraterone plus prednisone or methylprednisolone
 - 1st generation antiandrogens:
 - Nilutamide, flutamide, or bicalutamide
 - Ketoconazole ± prednisone, should not be used if the disease progressed on abiraterone
 - Corticosteroids (hydrocortisone, prednisone, dexamethasone)
 - DES or other estrogen
 - Antiandrogen withdrawal

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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)

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 (leuprolide acetate) subcutaneous injection

Lupron Depot (leuprolide acetate) intramuscular injection

Trelstar (triptorelin pamoate) intramuscular injection

Gonadotropin-releasing hormone antagonist:

Firmagon (dagarelix) subcutaneous injection

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

Zytiga (abiraterone acetate)

Erleada (apalutamide)

Bicalutamide

Xtandi (enzalutamide)

Flutamide

Nilutamide



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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

NCCN Compendium: Erleada (apalutamide) accessed 03-20-19



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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	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> 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

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

Incomplete forms or forms without the chart notes will be returned.

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