BlueCross BlueShield of Arizona
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**PHARMACY COVERAGE GUIDELINES**
**SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE: 1/01/16**
**LAST REVIEW DATE: 8/02/18**
**LAST CRITERIA REVISION DATE: 8/02/18**
**ARCHIVE DATE:**

# YONSA® (abiraterone acetate) oral tablet
# ZYTIGA® (abiraterone acetate) 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.**

## YONSA® (abiraterone acetate) oral tablet
## ZYTIGA® (abiraterone acetate) oral tablet (cont.)

**Criteria Initial therapy:** Zytiga (abiraterone acetate) and Yonsa (abiraterone acetate) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is an Oncologist

2. Individual is male and 18 years of age or older

3. A confirmed diagnosis of:
   - **For Yonsa**: metastatic castration-resistant prostate cancer
   - **For Zytiga**: metastatic castration-resistant prostate cancer **or** metastatic castration-sensitive prostate cancer

4. Will be used in combination with
   - **For Yonsa**: Methylprednisolone
   - **For Zytiga:** Prednisone

5. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
   - Comprehensive metabolic panel
   - Blood pressure is within normal limits, if abnormal medical treatment is started before beginning Zytiga or Yonsa
   - Left ventricular ejection fraction
   - Transaminases (AST and ALT) and bilirubin
   -

6. Will not be used in a patient with severe hepatic impairment (Child-Pugh Class C)

7. Will not be used in patients with New York Heart Association Class II-IV **or** in a patient with left ventricular ejection fraction of < 50%

8. There are **NO** contraindications
   - Contraindications include:
     - Pregnancy

**Initial approval duration:** 6 months

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

1. Continues to be seen by an Oncologist

2. Individual's condition responded while on therapy
   - Response is defined as:
     - No evidence of disease progression

## YONSA® (abiraterone acetate) oral tablet
## ZYTIGA® (abiraterone acetate) oral tablet (cont.)

- No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. Individual has not developed significant adverse drug effects such as:

5. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use, such as:
   - Severe hepatotoxicity
   - Excess mineralocorticoid effects
   - Adrenal insufficiency

6. There are no significant interacting drugs

**Renewal duration:** 12 months

**Description:**

Yonsa (abiraterone acetate) is a cytochrome P450 17 (CYP17, also known as 17 alpha-hydroxylase) inhibitor **indicated in combination with methylprednisolone for the treatment of metastatic castration-resistant prostate cancer (CRPC).**

Zytiga (abiraterone acetate) is a cytochrome P450 17 (CYP17, also known as 17 alpha-hydroxylase) inhibitor **indicated in combination with prednisone for the treatment of CRPC and for the treatment of castration-sensitive prostate cancer (CSPC)**.

CYP17 catalyzes two consecutive reactions: 1) the conversion of pregnenolone and progesterone to their 17alpha hydroxy derivatives by 17 alpha-hydroxylase and 2) the subsequent formation of dehydroepiandrosterone (DHEA) and androstenedione, respectively, by C17, 20 lyase. DHEA and androstenedione are androgens and are precursors of testosterone. CYP17 enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. Androgen sensitive prostatic carcinoma responds to treatment that decreases androgen levels. Androgen deprivation therapies, such as treatment with gonadotropin-releasing hormone (GnRH) agonists or orchiectomy, decrease androgen production in the testes but do not affect androgen production by the adrenals or in the tumor. Zytiga (abiraterone) decreases serum testosterone and other androgens.

**Resources:**

Zytiga. Package Insert. Revised by manufacturer 5/2015. Accessed 08-04-2015.

## YONSA® (abiraterone acetate) oral tablet
## ZYTIGA® (abiraterone acetate) oral tablet (cont.)

Zytiga. Package Insert. Revised by manufacturer 5/2016. Accessed 07-22-2016.

Zytiga. Package Insert. Revised by manufacturer 4/2017. Accessed 08-26-2017.

Zytiga (abiraterone) product information accessed 07-23-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4e338e89-3cf2-48eb-b6e2-a06c608c6513

Yonsa (abiraterone) product information accessed 07-23-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b8967e10-f768-47ce-ac9e-2324c8390132

NCCN Clinical Practice Guidelines in Oncology: Prostate cancer. Version 2.2017, Feb 21. 2017. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

UpToDate: Prostate cancer: Risk stratification and choice of initial treatment. Current through Aug 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/prostate-cancer-risk-stratification-and-choice-of-initial-treatment?source=search_result&search=prostate%20cancer&selectedTitle=1~150#H19

UpToDate: Overview of the treatment of castration-resistant prostate cancer (CRPC). Current through Aug 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-castration-resistant-prostate-cancer-crpc?source=search_result&search=prostate%20cancer&selectedTitle=3~150

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.

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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 |
|---|---|---|
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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.

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

Office notes, labs, and medical testing relevant to the request that show medical justification are required.