BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

Abiraterone Acetate
YONSA® (abiraterone acetate)
ZYTIGA® (abiraterone acetate)
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Yonsa (abiraterone acetate), Zytiga (abiraterone acetate), and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** 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. Individual has a confirmed diagnosis of **ONE** of the following:

a. **For Yonsa (abiraterone acetate) & generic (if available)**: metastatic castration-resistant prostate cancer (mCRPC)

b. **For Zytiga (abiraterone acetate) & generic abiraterone acetate: ONE** of the following:
   i. Metastatic castration-resistant prostate cancer (mCRPC) **or**
   ii. High-risk metastatic castration-sensitive prostate cancer (mCSPC)

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. Will be used in combination with:
   a. **For Yonsa (abiraterone acetate) & generic (if available)**: Methylprednisolone
   b. **For Zytiga (abiraterone acetate) & generic abiraterone acetate:** Prednisone

5. For **Zytiga or other generic abiraterone acetate**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic abiraterone acetate by CivicaScript** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. For **Yonsa <u>if available</u>:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Individual should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy (see Definitions section)

8. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
   a. Blood pressure is within normal limits if abnormal medical treatment is started before beginning therapy
   b. Eastern Cooperative Oncology Group (ECOG) Performance status is 0-1

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

10. Will not be used in patients with New York Heart Association (NYHA) Class II-IV heart failure **or** in a patient with left ventricular ejection fraction of less than 50%

<u>Initial approval duration</u>: 6 months

- **<u>Criteria for continuation of coverage (renewal request</u>** Yonsa (abiraterone acetate), Zytiga (abiraterone acetate), and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

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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 with response defined as there is no evidence of disease progression or unacceptable toxicity

3. Individual has been adherent with the medication

4. For **Zytiga or other generic abiraterone acetate**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or not a candidate for **generic abiraterone acetate by CivicaScript** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. For **Yonsa <u>if available</u>:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. Severe hepatoxicity
    b. Excess mineralocorticoid effects
    c. Adrenocortical insufficiency

7. Individual should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy

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

9. Will not be used in patients with New York Heart Association (NYHA) Class II-IV heart failure **or** in a patient with left ventricular ejection fraction of less than 50%

<u>Renewal duration</u>: 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 Non-Cancer Medications**

    2. **Off-Label Use of Cancer Medications**

ORIGINAL EFFECTIVE DATE: 01/01/2016 | ARCHIVE DATE: | LAST REVIEW DATE: 05/16/2024 | LAST CRITERIA REVISION DATE: 05/16/2024

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Description:

Abiraterone acetate is converted *in vivo* to abiraterone, an androgen biosynthesis inhibitor, that inhibits 17 α-hydroxylase/C17,20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. 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. Inhibition of CYP17 by abiraterone can also result in increased mineralocorticoid production by the adrenals.

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. Abiraterone decreases serum testosterone and other androgens.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

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
- 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)

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ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

NCCN recommendation definitions:

Category 1:
Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A:
Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B:
Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3:
Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

The Child-Pugh classification system:

The Child-Pugh classification is a scoring system used to determine the prognosis of individuals with cirrhosis. Scoring is based upon several factors: albumin, ascites, total bilirubin, prothrombin time, and encephalopathy, as follows:

	Score: 1 point	Score: 2 points	Score: 3 points
Serum Albumin (g/dL)	> 3.5	3.0 - 3.5	< 3.0
Serum Bilirubin (mg/dL)	< 2.0	2.0 - 3.0	> 3.0
Prothrombin time (seconds)	1 - 4	4 - 6	> 6
Ascites	none	moderate	severe
Encephalopathy	none	mild	severe

The three classes and their scores are:

- **Class A** is score 5 – 6: Well compensated
- **Class B** is score 7 – 9: Significant functional compromise
- **Class C** is score > 9: Decompensated disease

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Resources:

Abiraterone acetate product information, revised by Amneal Pharmaceuticals NY LLC. 12-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 08, 2024.

Yonsa (abiraterone acetate) product information, revised by Sun Pharmaceutical Industries, Inc. 07-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 08, 2024.

Zytiga (abiraterone acetate) product information, revised by Janssen Biotech, Inc. 08-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 08, 2024.

Dawson NA. Overview of the systemic treatment for recurrent or metastatic castration-sensitive prostate cancer. In: UpToDate, Lee WR, Richie JR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through April 2024. Topic last updated January 10, 2024. Accessed May 08, 2024.

Dawson NA, Leger P. Overview of the treatment of castration-resistant prostate cancer (CRPC). In: UpToDate, Lee WR, Richie JR, Sartor AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through April 2024. Topic last updated October 05, 2023. Accessed May 08, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer Version 3.2024 – Updated March 08, 2024. Available at https://www.nccn.org. Accessed May 08, 2024.

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.