PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/1/2016
LAST REVIEW DATE: 5/20/2021
LAST CRITERIA REVISION DATE: 5/20/2021
ARCHIVE DATE:

ABIRATERONE ACETATE
YONSA® (abiraterone acetate)
ZYTIGA® (abiraterone acetate)

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.**

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Criteria:

- **Criteria Initial therapy:** Generic abiraterone acetate, Yonsa (abiraterone acetate), and Zytiga (abiraterone acetate) are 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 male and 18 years of age or older

  3. A confirmed diagnosis of:
     a. **For Yonsa (abiraterone acetate)**: metastatic castration-resistant prostate cancer (mCRPC)

     b. **For Zytiga (abiraterone acetate) & generic abiraterone acetate**: mCRPC **or** 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)**: Methylprednisolone

     b. **For Zytiga (abiraterone acetate) & generic abiraterone acetate:** Prednisone

  5. Patients receiving generic abiraterone acetate, Yonsa (abiraterone acetate), or Zytiga (abiraterone acetate) should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy

  6. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Blood pressure is within normal limits, if abnormal medical treatment is started before beginning therapy

     b. Left ventricular ejection fraction

     c. Eastern Cooperative Oncology Group (ECOG) Performance status is 0-1

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

  8. 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%

  Initial approval duration: 6 months

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- **Criteria for continuation of coverage (renewal request):** Generic abiraterone acetate, Yonsa (abiraterone acetate) and Zytiga (abiraterone acetate) 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 responded while on therapy
     a. Response is defined as:
        i. No evidence of disease progression
        ii. 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 any significant adverse drug effects that may exclude continued use, such as:
     a. Severe hepatotoxicity

     b. Excess mineralocorticoid effects

     c. Adrenal insufficiency

  5. Patients receiving generic abiraterone acetate, Yonsa (abiraterone acetate), or Zytiga (abiraterone acetate) should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy

  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 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**

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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.

Resources:

Abiraterone acetate product information, revised by Mylan Pharmceuticals Inc. 01-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on March 15, 2021.

Yonsa (abiraterone acetate) product information, revised by Sun Pharmceutical Industries, Inc. 08-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on March 15, 2021.

Zytiga (abiraterone acetate) product information, revised by Janssen Biotech, Inc. 10-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on March 15, 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) Compendium: Abiraterone. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021(c); Available at: http://www.nccn.org. Accessed on March 15, 2021.

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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 15, 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.