VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Abiraterone Acetate (Zytiga® tablets – Janssen Biotech Inc.; generics [250 mg tablets only])

DATE REVIEWED: 02/19/2020; selected revision 03/04/2020

OVERVIEW

Abiraterone acetate is an androgen biosynthesis inhibitor that inhibits the enzyme 17 α-hydroxylase/C17, 20-lyase (CYP17).[1] This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. Abirateone acetate in combination with prednisone is indicated for use for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) and for the treatment of metastatic high-risk castration-sensitive prostate cancer (mCSPC). Inhibition of CYP17 by abiraterone acetate can also result in increased mineralocorticoid production by the adrenal glands; the use of prednisone with abiraterone acetate is to counteract this mineralocorticoid excess.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on prostate cancer (version 4.2019 – August 19, 2019) have the following recommendations for drug therapies (primarily focusing on oral agents, abiraterone acetate and Xtandi® [enzalutamide capsules]).[2]

- At initial diagnosis, for patients classified in the regional risk group (metastases in regional nodes [N1] with no distant metastases [M0]) and with a > 5 year expected patient survival or symptomatic, external beam radiation therapy (EBRT) + androgen deprivation therapy (ADT) [preferred] ± abiraterone acetate and prednisone is a recommended option (category 2A). ADT (without EBRT) ± abiraterone and prednisone is also a category 2A recommended option in this setting.
- If patients are positive for distant metastasis (M1) and have castration-naïve disease, ADT + abiraterone and prednisone and ADT + docetaxel are both category 1 recommended options. Other options are also available.
- For patients who progress to CRPC and are positive for distant metastasis, M1 and there are no visceral metastases, abiraterone and prednisone, docetaxel, Xtandi, and Xofigo® (radium Ra 223 dichloride injection, for intravenous use) [for symptomatic bone metastases] are all category 1 recommended options.
  - If there are visceral metastases, Xtandi and docetaxel are category 1 recommended options. Abiraterone and prednisone, mitoxantrone with prednisone, or other secondary hormone therapies are other options (all category 2A).
  - For no visceral metastases, if patients had received prior therapy with Xtandi or abiraterone, then docetaxel and Xofigo are the category 1 options for subsequent therapy. If patients received prior docetaxel therapy, then Xtandi, abiraterone, Xofigo, and cabazitaxel are the category 1 options. For subsequent therapy with visceral metastases, docetaxel is the recommended category 1 option, if either Xtandi or abiraterone were used as prior therapies. For prior therapy with docetaxel, Xtandi, abiraterone, cabazitaxel are the recommended category 1 options.

The STAMPEDE trial assessed the efficacy of abiratereone acetate and prednisone in combination with ADT in newly diagnosed patients with metastatic, node-positive, or high-risk locally advanced prostate cancer.[4] About 20% of the patients had node-positive non-metastatic disease. However, the guidelines note that there was insufficient data available for failure-free survival and follow-up to recommend abiraterone for men with high-risk or very high-risk N0 M0 prostate cancer and more data are needed.[2]

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of abiraterone acetate. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of abiraterone acetate is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Prostate Cancer – Metastatic, Castration-Resistant (mCRPC).** Approve for 3 years if the patient meets the following conditions (A and B):
   - **A)** The medication is used in combination with prednisone; AND
   - **B)** The patient meets ONE of the following criteria (i or ii):
     - **i.** The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog.
       Note: Examples are Lupron (leuprolide for injection), Lupron Depot (leuprolide acetate for depot suspension), Trelstar (triptorelin pamoate for injectable suspension), Zoladex (goserelin acetate implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix for injection); OR
     - **ii.** The patient has had a bilateral orchiectomy.

2. **Prostate Cancer –Metastatic, Castration-Sensitive (mCSPC).** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   - **A)** The medication is used in combination with prednisone; AND
   - **B)** The patient has high-risk disease (e.g., evidence of measurable visceral metastases, lesions on bone scan, total Gleason score ≥ 8) as confirmed by the prescribing physician; AND
   - **C)** The patient meets ONE of the following criteria (i or ii):
     - **i.** The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog.
       Note: Examples are Lupron (leuprolide for injection), Lupron Depot (leuprolide acetate for depot suspension), Trelstar (triptorelin pamoate for injectable suspension), Zoladex (goserelin acetate implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix for injection); OR
     - **ii.** The patient has had a bilateral orchiectomy.

Other Uses with Supportive Evidence

3. **Prostate Cancer – Regional Risk Group.** Approve for 3 years if the patient meets all of the following criteria (A, B, and C):
   - **A)** The medication is used in combination with prednisone; AND
   - **B)** Patient has regional lymph node metastases and no distant metastases; AND
   - **C)** Patient meets one of the following criteria (i or ii):
     - **i.** The medication with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) analog.
       Note: Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]), Firmagon (degarelix for injection); OR

ii. Patient has had an orchiectomy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Abiraterone acetate has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions are provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zytiga™ tablets [prescribing information]. Horsham, PA: Centocor Ortho Biotech, Inc; June 2019.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 4. 2019 – August 19, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 17, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 17, 2020. Search term: abiraterone acetate.
4. James ND, de Bono JS, Spears MR, et al. Abiraterone for prostate cancer not previously treated with hormone therapy. *N Engl J Med.* 2017;377:338-351.