MEDICAL MUTUAL®

Drug Policy

Policy:	Zytiga (abiraterone) Prior Approval Criteria	Annual Review Date: 06/22/2023 Last Revised Date: 06/22/2023

OVERVIEW

Abiraterone acetate, an androgen biosynthesis inhibitor, is indicated for following uses **in combination with prednisone**:[1]

- **Metastatic castration-resistant prostate cancer** (mCRPC).
- **Metastatic high-risk castration-sensitive prostate cancer** (mCSPC).

Guidelines

Abiraterone acetate is addressed in National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 1.2023 – September 16, 2022) in a variety of clinical settings:

- For initial therapy for patients in the very-high-risk group, abiraterone acetate + prednisone + external beam radiation therapy (EBRT) and 2 years of androgen deprivation therapy (ADT) if the life expectancy is > 5 years or the patient is symptomatic is recommended (category 2A).
- For initial therapy 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, preferred therapy is EBRT + ADT + abiraterone acetate + prednisone (category 2A). ADT (without EBRT) ± abiraterone + prednisone is also recommended in this setting (category 2A). Abiraterone + ADT should be considered for a total of 2 years for those patients with N1 disease who are treated with radiation to the prostate and pelvic nodes. ADT in this setting includes orchiectomy, gonadotropin-releasing hormone (GnRH), or degarelix.
- For patients who are positive for distant metastasis (M1) and have castration-naïve disease, ADT + abiraterone + prednisone is a preferred recommendation (category 1).
- For patients with M0, prostate specific antigen (PSA) persistence or recurrence after radical prostatectomy with pelvic recurrence and life expectancy > 5 years, abiraterone + prednisone + ADT is recommended (category 2A). PSA persistence/recurrence after radical prostatectomy is defined as failure of PSA to fall to undetectable levels (PSA persistence) or undetectable PSA after radical prostatectomy with a subsequent detectable PSA that increases on 2 or more determinations (PSA recurrence) or that increases to PSA > 0.1 ng/mL.
- For patients who progress to castration-resistant prostate cancer and are positive for distant metastasis (M1) with no visceral metastases, abiraterone + prednisone is a preferred regimen (category 1) for patients who have not received prior novel hormone therapy (category 1). For patients who have received prior novel hormone therapy, abiraterone + prednisone is recommended (category 2A); abiraterone +dexamethasone is recommended in this setting for patients who have not received docetaxel if patients have had disease progression on either formulation of abiraterone (category 2A).

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POLICY STATEMENT

This policy involves the use of abiraterone acetate. Prior authorization is recommended for pharmacy benefit coverage of Abiraterone acetate. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Abiraterone acetate as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Abiraterone acetate be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist, urologist, or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of abiraterone acetate or Zytiga is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

For all indications: If the request is for brand Zytiga, the patient has trialed the generic product and/or the patient cannot take the generic due to a formulation difference in the active ingredient or due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and the generic product which would result in a significant allergy or serious adverse reaction per the prescribing physician [documentation required].

1. **Prostate Cancer – Metastatic, Castration-Resistant (mCRPC).** Approve if the patient meets the following conditions (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is used in combination with prednisone or dexamethasone; AND
   - **C)** Patient meets ONE of the following criteria (i, ii, or iii):
     - **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), Orgovyx (relugolix tablets); OR
     - **ii.** The medication is concurrently used with Firmagon (degarelix for injection); OR
     - **iii.** Patient has had a bilateral orchiectomy.

2. **Prostate Cancer –Metastatic, Castration-Sensitive (mCSPC).** Approve if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is used in combination with prednisone; AND
   - **C)** Patient meets ONE of the following criteria (i, ii, or iii):

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), Orgovyx (relugolix tablets); OR
ii. The medication is concurrently used with Firmagon (degarelix for injection); OR
iii. Patient has had a bilateral orchiectomy.

Other Uses with Supportive Evidence

3. **Prostate Cancer – Radical Prostatectomy**. Approve for 1 year if the patient meets all of the following criteria (A, B, C, D, and E):
   a. Patient is ≥ 18 years of age; AND
   b. The medication is used in combination with prednisone; AND
   c. Patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy; AND
   d. Patient has pelvic recurrence; AND
   e. Patient meets one of the following criteria (i, ii, or iii):
      i. The medication is concurrently used with gonadotropin-releasing hormone (GnRH) agonist; OR
      Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
      ii. The medication is used in combination with Firmagon (degarelix subcutaneous injection); OR
      iii. Patient has had a bilateral orchiectomy.

4. **Prostate Cancer – Regional Risk Group.** Approve if the patient meets all of the following criteria (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) The medication is used in combination with prednisone; AND
   C) Patient has regional lymph node metastases and no distant metastases; AND
   D) Patient meets one of the following criteria (i, ii, or iii):
      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), Orgovyx (relugolix tablets); OR
      ii. The medication is concurrently used with Firmagon (degarelix for injection); OR
      iii. Patient has had a bilateral orchiectomy.

5. **Prostate Cancer – Very-High-Risk Group**. Approve if the patient meets all of the following criteria (A, B, C, D, and E):

A) Patient is ≥ 18 years of age; AND
B) The medication is used in combination with prednisone; AND
C) According the prescriber, the patient is in the very-high-risk group; AND
Note: Very-high-risk group includes patients that have one of the following: primary Gleason pattern 5; 2 or 3 high-risk features; >4 cores with Grade Group 4 or 5; tumor that invades seminal vesicles; tumor that is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall.
D) The medication is used in combination with external beam radiation therapy; AND
E) Patient meets one of the following criteria (i, ii, or ii):
- **i.** The medication is concurrently used with gonadotropin-releasing hormone (GnRH) agonist; OR
  Note: Examples of GnRH agonists include: 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).
- **ii.** The medication is used in combination with Firmagon (degarelix for injection); OR
- **iii.** Patient has had a bilateral orchiectomy.

5. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.** Prescriber will provide specific diagnosis for documentation. Approve.

6. **Patient has been started on Zytiga.** Approve for an indication or condition addressed as an approval in this document.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Zytiga 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. (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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical

necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- Zytiga® [prescribing information]. Horsham Township, PA: Janssen Biotech, Inc; June 2019.
- The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 12, 2022.
- The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 1. 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 8, 2018.The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 1. 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 8, 2018.James ND, de Bono JS, Spears MR, et al. Abiraterone for prostate cancer not previously treated with hormone therapy. N Engl J Med. 2017, June 3 [Epub ahead of print].
- Fizazi K, Tran NP, Fein L, et al. Abiraterone plus prednisone in metastatic, castration-sensitive prostate cancer. *N Engl J Med.* 2017, June 4 [Epub ahead of print].