

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Abiraterone Acetate Prior Authorization Policy

- Abiraterone Acetate (Zytiga® tablets – Janssen Biotech, generic)

REVIEW DATE: 08/07/2024

OVERVIEW

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

- **Metastatic castration-resistant prostate cancer.**
- **Metastatic castration-sensitive prostate cancer, high-risk.**

Guidelines

Abiraterone acetate is addressed in National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 4.2023 – September 7, 2023) 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 (CRPC) 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). For BRCA mutation-positive metastatic CRPC, abiraterone in combination with Lynparza® (olaparib tablets) or Zejula® (niraparib capsules) are both category 1 recommended therapies listed as “useful in certain circumstances” if patient had no prior docetaxel or no prior novel hormone therapy. It is a category 2A recommendation if patients had prior docetaxel and no prior novel hormone therapy. Abiraterone + Zejula is a category 2B recommendation for prior novel hormone therapy and no prior docetaxel therapy.

POLICY STATEMENT

08/07/2024

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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 one of the following criteria:

FDA-Approved Indication

1. Prostate Cancer – Metastatic, Castration-Resistant. Approve for 1 year if the patient meets ALL of the following (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 (i or ii):

i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog; OR
Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant); Firmagon (degarelix subcutaneous injection); Orgovyx (relugolix tablets).

ii. Patient has had a bilateral orchiectomy.

2. Prostate Cancer – Metastatic, Castration-Sensitive. Approve for 1 year if the patient meets ALL of the following (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 (i or ii):

i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog; OR
Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant); Firmagon (degarelix subcutaneous injection); Orgovyx (relugolix tablets).

ii. Patient has had a bilateral orchiectomy.

Other Uses with Supportive Evidence

3. Prostate Cancer – Post Radical Prostatectomy or Radiation Therapy. Approve for 1 year if the patient meets ALL of the following (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 meets ONE of the following (i or ii):

i. Patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy; OR

ii. Patient has PSA recurrence or positive digital rectal examination (DRE) after radiation therapy;
AND

D) Patient has pelvic nodal recurrence or positive regional lymph nodes; AND

E) Patient meets ONE of the following (i or ii):

i. The medication is concurrently used with gonadotropin-releasing hormone (GnRH) analog; OR

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: Janssen Biotech; August 2021.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 5, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 5, 2024. Search term: abiraterone acetate.