PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Abiraterone Acetate Prior Authorization Policy
- Abiraterone Acetate (Zytiga® tablets – Janssen Biotech, generic)

REVIEW DATE: 08/07/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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

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

- **Abiraterone Acetate (Zytiga® tablets (Janssen Biotech, generic) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

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
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.

4. Prostate Cancer – Regional Risk Group. Approve for 1 year if the patient meets ALL of the following (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 (i or ii):
i. The medication is concurrently used with 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.

5. **Prostate Cancer – Very-High-Risk Group**. Approve for 2 years (total) 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) According to the prescriber, the patient is in the very-high-risk group; AND
Note: Very-high-risk group includes patients who 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 (i or ii):
i. The medication is concurrently used with gonadotropin-releasing hormone (GnRH) analog; OR
Note: Examples are leuprolide injection, 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.

6. Salivary Gland Tumors. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) The medication is used in combination with prednisone; AND
C) The patient has androgen receptor-positive (AR+) recurrent, unresectable or metastatic tumor; AND
D) The medication is used in combination with gonadotropin-releasing hormone (GnRH) analog.
Note: Examples are leuprolide injection, 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).

CONDITIONS NOT COVERED

- **Abiraterone Acetate (Zytiga® tablets (Janssen Biotech, generic) is(are) considered experimental, investigational or unproven for ANY other use(s); 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	12/20/2023
Early Annual Revision	For **ALL** indications in this policy the following changes apply. The criterion requiring the trial of gonadotropin-releasing hormone "agonist" was changed to "analog," which allows use of both agonists and antagonists. Firmagon and Orgovyx were added as examples in the Note. The separate criterion previously asking for concurrent use of medication with Firmagon was deleted since it is no longer needed. **Prostate Cancer – Radical Prostatectomy:** Added qualifier "Post" Radical Prostatectomy and added qualifier "or Radiation Therapy" to indication. Added criterion "Patient has prostate-specific antigen (PSA) recurrence or positive digital rectal examination (DRE) after radiation therapy." Clarified pelvic recurrence to pelvic "nodal" recurrence and added criterion "or positive regional lymph nodes." **Salivary Gland Tumors:** Added new condition of approval and criterion under "Other Uses with Supportive Evidence."	08/07/2024