UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 1120-11 |
| Program | Prior Authorization/Notification |
| Medication | Zytiga® (abiraterone acetate) |
| P&T Approval Date | 9/2011, 8/2012, 2/2013, 7/2013, 11/2014, 11/2015, 9/2016, 9/2017, 5/2018, 5/2019, 5/2020, 5/2021, 5/2022, 5/2023 |
| Effective Date | 8/1/2023;<br>Oxford only: 8/1/2023 |

**1. Background:**

Zytiga® (abiraterone acetate) is a CYP17 inhibitor indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer and for high-risk metastatic castration-sensitive prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Zytiga or should have had bilateral orchiectomy.[1] The National Comprehensive Cancer Network (NCCN) also recommends the use of Zytiga in combination with prednisone and androgen deprivation therapy as initial therapy for patients without metastases yet with regional node positive disease, in combination with androgen deprivation therapy (ADT) and external bean radiation therapy (EBRT) as initial therapy in patients with very-high-risk, node negative prostate cancer, and in combination with prednisone and ADT in patients with positive pelvic persistence/recurrence after prostatectomy. [2]

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria[a]:**

**A. <u>Patients less than 19 years of age</u>**

1. **Zytiga** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   **Authorization will be issued for 12 months.**

**B. <u>Prostate Cancer</u>**

1. **<u>Initial Authorization</u>**

   a. **Zytiga** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of prostate cancer

**-AND-**

(2) **One** of the following:

(a) Disease is metastatic

**-OR-**

(b) Disease is regional node positive (Any T, N1, M0)

**-OR-**

(c) Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT)

**-OR-**

(d) Positive pelvic persistence/recurrence after prostatectomy

**-AND-**

(3) Used in combination with prednisone or dexamethasone

**-AND-**

(4) **One** of the following:

(a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

**-OR-**

(b) Patient has had bilateral orchiectomy

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Zytiga** will be approved based on the following criterion:

   a. Patient does not show evidence of progressive disease while on Zytiga therapy

**Authorization will be issued for 12 months.**

**C. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a

Category of Evidence and Consensus of 1, 2A, or 2B

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Zytiga [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 23, 2023.


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| **Change Control** | |
| 11/2014 | Annual review with no change to coverage. Updated references. |
| 11/2015 | Annual review. Minor revision to prostate cancer criteria. Updated background & references. |
| 9/2016 | Annual review. Updated references. |
| 9/2017 | Annual review with no changes to coverage criteria. Updated references. |
| 5/2018 | Updated background and criteria to include new indication for metastatic castration-sensitive disease and NCCN recommended use in regional node positive disease. |
| 5/2019 | Annual review with no changes to coverage criteria. Updated references. |
| 5/2020 | Annual review. Added general NCCN recommendations for use criteria. Updated references. |
| 5/2021 | Annual review. Added patient has not shown progression of disease while on another formulation of abiraterone to coverage criteria per NCCN recommendations. Updated references. |
| 5/2022 | Annual review. Added criteria for use in combination with EBRT in very-high-risk groups and removed patient has not shown progression of disease while on another formulation per NCCN recommendations. Updated references. |
| 5/2023 | Annual review. Added positive pelvic persistence/recurrence after prostatectomy and added dexamethasone. Changes based on NCCN |

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| | recommendations. Added state mandate footnote. Updated reference. |