UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zytiga

Program	Prior Authorization
Medication	Zytiga™ (abiraterone acetate)
Markets in Scope	Arizona, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, South Carolina, Rhode Island, California
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	1/2020
Effective Date	3/2020

NOTE: Zytiga 500mg is non-preferred

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.[2]

2. Coverage Criteria:

A. <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) **<u>One</u>** of the following:

(a) Disease is metastatic

-OR-

(b) Disease is regional node positive (e.g., N1)

-AND-

(3) Used in combination with prednisone

-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

-AND-

(5) If the request is for the 500mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250mg

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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Zytiga** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Zytiga therapy

Authorization will be issued for 12 months.

3. References:

1. Zytiga [package insert]. Horsham, PA: Janssen Biotech Inc.; June 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed December 3, 2019.

Program	Prior Authorization - Zytiga (abiraterone acetate)
Change Control	
Date	Change
9/2013	New policy
9/2016	Updated clinical criteria to align with E&I notification policy and updated policy template.
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. Added NCCN recommended regimen review criteria. Updated references.
1/2019	Added note that Zytiga 500mg is non-preferred. Added reason or special circumstance the patient cannot take abiraterone 250mg prior to receiving approval for Zytiga 500mg.
1/2020	Annual review. Updated references.