

Commercial PA Criteria

Effective: January 1, 2020

Prior Authorization: Abiraterone acetate

Products Affected: Abiraterone acetate oral tablets, Zytiga oral tablets (brand name), Abirtega (abiraterone acetate) oral tablets

Medication Description:

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.

Zytiga is converted in vivo to abiraterone, an androgen biosynthesis inhibitor, that inhibits 17 α -hydroxylase/C17,20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. CYP17 catalyzes two sequential reactions: 1.) the conversion of pregnenolone and progesterone to their 17 α -hydroxy derivatives by 17 α -hydroxylase activity and 2.) the subsequent formation of dehydroepiandrosterone (DHEA) and androstenedione, respectively, by C17, 20 lyase activity. DHEA and androstenedione are androgens and are precursors of testosterone. Inhibition of CYP17 by abiraterone can also result in increased mineralocorticoid production by the adrenals.

Covered Uses:

1. Metastatic castration-resistant prostate cancer (CRPC)
2. Metastatic high-risk castration-sensitive prostate cancer (CSPC)

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Medical history
3. Previous therapies tried
4. Current therapy regimen

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 3 years

Other Criteria:

Metastatic castration-resistant prostate cancer (CRPC)

- A. Patient has diagnosis of Metastatic castration-resistant prostate cancer (CRPC); **AND**
- B. Patient will receive a GnRH-analog or has had a bilateral orchiectomy; **AND**

Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas

March 2025



Confidential Information

This document is confidential and proprietary to EmblemHealth. Unauthorized use and distribution are prohibited.

(histrelin acetate subcutaneous implant); Firmagon (degarelix subcutaneous injection); Orgovyx (relugolix tablets).

- C. Patient is taking requested medication in combination with prednisone or dexamethasone
Note: If requesting brand name Zytiga: Patient must have an intolerance or contraindication to generic abiraterone acetate.

Metastatic high-risk castration-sensitive prostate cancer (CSPC)

- A. Patient has diagnosis of Metastatic high-risk castration-sensitive prostate cancer (CSPC); **AND**
 B. Patient will receive a GnRH-analog or has had a bilateral orchiectomy; **AND**
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).
 C. Patient is taking requested medication in combination with prednisone or dexamethasone
Note: If requesting brand name Zytiga: Patient must have an intolerance or contraindication to generic abiraterone acetate.

References:

1. Zytiga [package insert]. Horsham, PA: Janssen Biotech Inc.; May 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 27, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/1/2020
2	Update	Added Zytiga oral brand name tablets to products affected Other criteria: Added: For Zytiga oral tablets requests only: Patient has an intolerance or contraindication to abiraterone acetate oral tablets	Products affected Other criteria	05/29/2020
3	Update	Added Abirtega (abiraterone acetate) oral tablets to products affected. Added "or dexamethasone" in the criteria 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. Examples included in NOTE	Products affected Other criteria	3/31/2025