Zytiga (abiraterone acetate)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Zytiga (abiraterone acetate) Abirtega (abiraterone acetate)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Zytiga (abiraterone acetate) or Abirtega (abiraterone acetate) may be approved if the following are met (Label, NCCN 1, 2A):

I. Individual is using in combination with prednisone;

AND

II. Individual is diagnosed with one of the following:
   A. Metastatic castration-resistant* prostate cancer (CRPC); **OR**
   B. Individual is diagnosed with Metastatic castration-sensitive prostate cancer (CSPC);

AND

III. One of the following:
   A. Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron (leuprolide, Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix); **OR**
   B. Individual has had a bilateral orchiectomy;

OR

IV. Individual is diagnosed with non-metastatic very-high risk prostate cancer (NCCN 2A); **AND**
   A. Individual has a life expectancy of greater than 5 years or symptomatic; **AND**
   B. Individual is using with external beam radiation therapy (EBRT) and 2 years of androgen deprivation therapy (ADT); **AND**
   C. Individual is using in combination with prednisone;

OR

V. Individual is diagnosed with metastatic castration-resistant* prostate cancer (mCRPC) (Label, NCCN 1, 2A); **AND**

VI. Individual has deleterious or suspected deleterious BRCA-mutation (BRCAm); **AND**

VII. Individual is using in combination with prednisone or prednisolone; **AND**

VIII. Individual is using in combination with Lynparza (olaparib);

OR

IX. Individual is using for recurrent, unresectable, or metastatic salivary gland tumors (NCCN 2A); **AND**

X. Individual has androgen receptor positive tumors (AR+); **AND**
XI. Individual cannot have surgery or radiotherapy; **AND**
XII. Individual is using abiraterone plus prednisone.

Requests for **brand** Zytiga must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Individual has failed an adequate trial of one chemically equivalent generic abiraterone acetate agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
AND
   A. Generic abiraterone acetate had inadequate response; **OR**
   B. Generic abiraterone acetate caused adverse outcome; **OR**
   C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Requests for Zytiga (abiraterone acetate) or Abirtega (abiraterone acetate) may not be approved for the following:

I. Individual is using the alternative agent Yonsa (fine-particle abiraterone acetate) with methylprednisolone for metastatic CRPC.

*Castration-resistant refers to disease progression following either surgically or medically-induced methods of castration. Medically-induced methods of castration include luteinizing hormone-releasing hormone (LHRH) agonists (such as leuprolide and goserelin) or LHRH antagonists (such as degarelix).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 20, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 20, 2024.
   a. Head and Neck Cancers. V4.2024. Revised May 1, 2024.
   b. Prostate Cancer. V4.2024. Revised May 17, 2024.