

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. 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 or regional risk (Any T, N1, MO) prostate cancer (NCCN 2A, DP B I); **AND**
 - A. Individual is diagnosed with a life expectancy of greater than 5 years or symptomatic; **AND**
 - B. One of the following:
 1. Individual in the very high-risk group is using with external beam radiation therapy (EBRT) and 2 years of androgen deprivation therapy (ADT); **OR**
 2. Individual in the regional risk group is using with androgen deprivation therapy;

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 in combination with Zejula (niraparib) as a substitute for the combination Akeega (niraparib/abiraterone) tablet;

OR

- X. Individual is diagnosed with metastatic castration-resistant prostate cancer (mCRPC) (NCCN 2A); **AND**
XI. Individual is using abiraterone with dexamethasone;

OR

- XII. Individual is using for recurrent, unresectable, or metastatic salivary gland tumors (NCCN 2A); **AND**
XIII. Individual has androgen receptor positive tumors (AR+); **AND**
XIV. Individual cannot have surgery or radiotherapy; **AND**
XV. Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron [leuprolide], Zoladex [goserelin], Trelstar [triptorelin], Vantas [histrelin], Firmagon [degarelix]); **AND**
XVI. Individual is using abiraterone plus prednisone.

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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 28, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 28, 2025.
 - a. Head and Neck Cancers. V4.2025. Revised June 20, 2025.
 - b. Prostate Cancer. V1.2025. Revised June 3, 2025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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