

Title: *abiraterone (Zytiga)*

Origination: 08/24/11	Revised:	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Abiraterone is an antiandrogen antineoplastic indicated for the treatment of metastatic, castration-resistant prostate cancer in patients previously treated with docetaxel.
- Abiraterone irreversibly inhibits cytochrome P450 17A1 (17-alpha-hydroxylase/C17,20-lyase), an enzyme that is required for androgen biosynthesis and expressed in testicular, adrenal and prostatic tumor tissues.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Member must be over the age of 18 years.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Procedure:

- 1.0 Request for *initial therapy* with Zytiga (abiraterone) for metastatic, castrate-resistant prostate cancer requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 1.1 Prescriber must be an oncologist; **AND**
 - 1.2 Member must have diagnosis of metastatic, castrate-resistant prostate cancer; **AND**
 - 1.3 Member shows inadequate response to a three (3) to six (6) month minimum trial of docetaxel (Taxol) therapy; **AND**
 - 1.4 If Member meets all criteria, Zytiga 1000mg daily, given with prednisone, may be approved for six (6) months.

- 2.0 Request for *continuation of therapy* with Zytiga (abiraterone) for metastatic, castrate-resistant prostate cancer requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 2.1 Member is responding to treatment; **AND**
 - 2.2 If Member meets all criteria, Zytiga 1000mg daily, given with prednisone, may be approved for 12 months.

References:

1. Zytiga [Prescribing Information]. Centocor Ortho Biotech, Inc. Horsham, PA. April 2011.
2. FDA News Release. FDA approves Zytiga for late-stage prostate cancer. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm253055.htm>. Accessed May 9, 2011.
3. Sartor AO. Progression of metastatic castrate-resistant prostate cancer: impact of therapeutic intervention in the post-docetaxel space. J Hematol Oncol. 2011; 4(1):18.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.