

SPECIALTY GUIDELINE MANAGEMENT

ZYTIGA (abiraterone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Zytiga is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.

B. Compendial Uses

Zytiga can be used in combination with prednisone and androgen-deprivation therapy for the treatment of patients with newly diagnosed, metastatic, high-risk hormone-sensitive prostate cancer.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Metastatic castration-resistant prostate cancer**

Authorization of 12 months may be granted for the treatment of metastatic castration-resistant prostate cancer when all of the following criteria are met:

- 1) Patient has been previously treated with enzalutamide unless the patient has a contraindication to enzalutamide therapy.
- 2) The requested drug will be used in combination with prednisone.

B. **Castration-sensitive metastatic or locally advanced prostate cancer**

Authorization of 12 months may be granted for the treatment of castration-sensitive metastatic or locally advanced prostate cancer when all of the following criteria are met:

- 1) The requested drug will be used in combination with prednisone and concurrent androgen-deprivation therapy. Androgen deprivation therapy is not required in patients who have had bilateral orchiectomy.
- 2) Disease is newly diagnosed and metastatic, node-positive, high-risk locally advanced, or was previously treated with radical surgery or radiotherapy and is now relapsing with high risk features.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Zytiga [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2017.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed August 3, 2017.
3. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed August 3, 2017.

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4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Prostate Cancer (Version 2.2017). <http://www.nccn.org>. Accessed July 17, 2017.

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