Reference number(s)
1934-A

SPECIALTY GUIDELINE MANAGEMENT

ZYTIGA (abiraterone)
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 Indications
   1. Indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).
   2. Indicated in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer (CSPC).

B. Compendial Uses
   1. Node-positive (N_1), non-metastatic (M_0) prostate cancer
   2. High-risk, non-metastatic prostate cancer
   3. Very-high-risk prostate cancer
   4. Non-metastatic (M_0) prostate cancer with prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy
   5. Salivary gland tumor

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided if the requested medication is used in combination with a second-generation oral anti-androgen (e.g., apalutamide [Erleada]) or an oral androgen metabolism inhibitor (e.g., fine-particle abiraterone acetate [Yonsa]).

III. CRITERIA FOR INITIAL APPROVAL

A. Prostate Cancer

Authorization of 12 months may be granted for the treatment of prostate cancer when both of the following criteria are met:
   1. The member has had a bilateral orchiectomy or will be using the requested medication with a GnRH agonist or degarelix
   2. The member meets either of the following criteria:

i. The disease is non-metastatic and the disease is node positive, high-risk, very-high-risk or has prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy
ii. The disease is metastatic

B. Salivary Gland Tumor
Authorization of 12 months may be granted for treatment of recurrent salivary gland tumor as a single agent when the tumor is androgen receptor positive.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Zytiga [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2021.
2. Abiraterone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2021.
3. IBM Micromedex®DRUGDEX® (electronic version). IBM Watson Heath, Greenwood Village, Colorado. Available at https://www.micromedexsolutions.com. Accessed August 6, 2023.
4. The NCCN Drugs & Biologics Compendium™ © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed October 10, 2023.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Prostate Cancer (Version 2.2023). https://www.nccn.org. Accessed August 6, 2023.