

| |
|---------------------|
| 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 Indication

1. Indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.
2. Indicated in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer.

B. Compendial Uses

Node-positive (N₁), non-metastatic (M₀) prostate cancer

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

Authorization of 12 months may be granted for the treatment of node positive or metastatic prostate cancer when the member has had a bilateral orchiectomy or will be using the requested medication in combination with a GnRH analog.

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.

| |
|---------------------|
| Reference number(s) |
| 1934-A |

V. REFERENCES

1. Zytiga [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2019.
2. Abiraterone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; June 2019.
3. IBM Micromedex®DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at <https://www.micromedexsolutions.com>. Accessed July 19, 2020.
4. The NCCN Drugs & Biologics Compendium™ © 2020 National Comprehensive Cancer Network, Inc. <https://www.nccn.org> Accessed July 19, 2020.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Prostate Cancer (Version 2.2019). <https://www.nccn.org>. Accessed July 19, 2020.