

Generic Name: Abiraterone

Therapeutic Class or Brand Name: Zytiga

Applicable Drugs (if Therapeutic Class): N/A

Preferred: abiraterone acetate (generic)

Non-preferred: Zytiga (brand)

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 1/12/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documented diagnosis of ONE of the following conditions:
 - A. Metastatic castration-resistant prostate cancer (mCRPC).
 - B. Metastatic high-risk castration-sensitive prostate cancer (CSPC).
- II. Zytiga will be used in combination with prednisone.
- III. Patient is using a gonadotropin-releasing hormone (GnRH) analog concurrently or has had bilateral orchiectomy.
- IV. Minimum age requirement: 18 years old.
- V. Treatment must be prescribed by or in consultation with an oncologist or urologist.
- VI. Medication is prescribed in accordance with FDA labeling or current clinical practice guidelines
- VII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Female patients

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 250 mg strength: 120 tablets per 30 days.
- 500 mg strength: 60 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Zytiga. Prescribing Information. Janssen Biotech; 2021. Accessed January 12, 2024. <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ZYTIGA-pi.pdf>
2. Schaeffer E, Srinivas S, et al., NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Prostate Cancer. NCCN. 2023; version 4.2023: Pros-1 – MS-138. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.