

Generic Name: Enzalutamide

Therapeutic Class or Brand Name: Xtandi

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 1/15/2024

PRIOR AUTHORIZATION CRITERIA

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

- I. Documentation of one of the following A. or B.
 - A. Diagnosis of castration-resistant prostate cancer (CRPC) or metastatic castration-sensitive prostate cancer (MCSPC) with i) or ii)
 - i. Concurrent treatment with a gonadotropin-releasing hormone (GnRH) analog
 - ii. Historical bilateral orchiectomy.
 - B. Diagnosis of non-metastatic castration sensitive prostate cancer (CSPC) with biochemical recurrence at high risk for metastasis
- II. Prior treatment with abiraterone (Zytiga®) has been ineffective, contraindicated, or not tolerated.
- III. Minimum age requirement: 18 years old.
- IV. Prescriber is an oncologist or urologist.
- V. 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

- 40 mg capsules, 40 mg tablets: 120 capsules per 30 days.
- 80 mg tablets: 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. Xtandi. Prescribing Information. Astellas Pharma; November 2023. Available at: <https://www.astellas.us/docs/us/12A005-ENZ-WPI.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.