

Applicable Drugs: Xtandi (enzalutamide)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 7/3/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI 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. Must be able to swallow tablet/capsule whole
- III. Minimum age requirement: 18 years old.
- IV. Treatment must be prescribed by or in consultation with an oncologist or urologist.
- V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Female patients.

OTHER CRITERIA

- Avoid strong CYP2C8 inhibitors. If coadministration cannot be avoided, reduce the dosage to 80 mg once daily
- Avoid strong CYP3A4 Inducers. If coadministration cannot be avoided, increase the dosage from 160 mg to 240 mg orally once daily
- May not chew, dissolve, or open the capsules nor cut, crush, or chew tablet formulation

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 40 mg capsules/tablets
 - Max 120 capsules per 30 days
 - Max 180 capsules per 30 days if concomitantly given with CYP3A4 inducer
- 80 mg tablets
 - Max 60 tablets per 30 days
 - Max 90 tablets per 30 days if concomitantly given with CYP3A4 inducer

APPROVAL LENGTH

- **Authorization:** 12 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Xtandi. Prescribing Information. Astellas Pharma; 2025. Accessed 7/3/2025.
<https://www.astellas.us/docs/us/12A005-ENZ-WPI.pdf>.
2. NCCN Clinical Practice Guidelines in Oncology. Prostate Cancer. V.2. 2025. Updated April 16, 2025. Accessed July 3, 2025. 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.