

Xtandi (enzalutamide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Xtandi (enzalutamide) 40 mg capsule or tablet	4 capsules or tablets per day
Xtandi (enzalutamide) 80 mg tablet	2 tablets per day

For coadministration with a strong CYP3A4 inducer, may allow 240 mg once daily dosage.

APPROVAL CRITERIA

Requests for Xtandi (enzalutamide) may be approved if the following is met:

- I. Individual is diagnosed with one of the following:
 - A. Individual has a diagnosis of M1 (distant metastasis) castration-resistant* prostate cancer (CRPC) (Label, NCCN 2A);

OR

- B. Individual has a diagnosis of M0 (no distant metastasis) castration-resistant* prostate cancer (CRPC) (Label, NCCN 1); **AND**
- C. Individual has a PSA doubling time (PSADT) \leq 10 months;

OR

- D. Individual has a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC);

OR

- E. Individual has a diagnosis of metastatic castration-resistant* prostate cancer (mCRPC); **AND**
- F. Individual has homologous recombination repair (HRR) mutation including ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C; **AND**
- G. Using in combination with talazoparib (Talzenna);

AND

- II. One of the following:
 - A. Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron (leuprolide, Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix); **OR**
 - B. Individual has had a bilateral orchiectomy;

OR

- III. Individual has a diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR).

*Castration-resistant refers to disease progression following either surgically or medically induced methods of castration. Medically-induced methods of castration include luteinizing hormone-releasing hormone (LHRH) agonists (such as leuprolide and goserelin) or LHRH antagonists (such as degarelix).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 13, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 13, 2023.
 - a. Prostate Cancer. V1.2023. Revised September 16, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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