

Specialty Guideline Management

Xtandi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xtandi	enzalutamide

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.

FDA-approved Indications¹

Xtandi is indicated for the treatment of patients with:

- Castration-resistant prostate cancer (CRPC)
- Metastatic castration-sensitive prostate cancer (mCSPC)
- Non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR)

Compendial Uses²

Prostate Cancer

All other indications are considered experimental/investigational and not medically necessary.

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., abiraterone acetate [Zytiga]).

Coverage Criteria

Castration-resistant prostate cancer (CRPC)^{1,2}

Authorization of 12 months may be granted for the treatment of castration-resistant prostate cancer when the member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (degarelix, relugolix).

Metastatic castration-sensitive prostate cancer (mCSPC)^{1,2}

Authorization of 12 months may be granted for the treatment of metastatic castration-sensitive prostate cancer when the member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (degarelix, relugolix).

Non-metastatic castration-sensitive prostate cancer (nmCSPC)^{1,2}

Authorization of 12 months may be granted for the treatment of non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; March 2025.
2. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 12, 2025.