

Commercial/Healthcare Exchange PA Criteria

Effective: May 4, 2016

Prior Authorization: Xtandi

Products Affected: Xtandi (enzalutamide) oral capsules

Medication Description:

Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).¹ Xtandi effects different steps in the androgen receptor signaling pathway. It competitively inhibits androgen binding to androgen receptors and inhibits androgen receptor nuclear translocation and interaction with DNA. Xtandi decreased proliferation of prostate cancer cells *in vitro* and induced cell death. In animal models, Xtandi also decreased tumor volume.

Covered Uses:

1. Castration-resistant prostate cancer
2. Metastatic castration-sensitive prostate cancer

Exclusion Criteria: N/A

Required Medical Information:

1. Previous therapies tried
2. Dose and frequency

Age Restrictions: 18 years of age and older

Prescriber Restrictions: None

Coverage Duration: 12 Months

Other Criteria:

1. Castration-Resistant Prostate Cancer (CRPC)

- A) The patient has metastatic castration-resistant prostate cancer
- B) Patients must try and fail Zytiga (abiraterone acetate) prior to treatment with Xtandi capsules

2. Metastatic castration-sensitive prostate cancer

- A. The patient has metastatic castration-sensitive prostate cancer; AND
- B. If the patient's diagnosis is high risk, the patient must try and fail Zytiga (abiraterone acetate) prior to treatment with Xtandi capsules

References:

1. Xtandi [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; February 2016.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 1.2015). © 2015 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 22, 2016.

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/13/2020