Clinical Policy: Enzalutamide (Xtandi)

Reference Number: PA.CP.PHAR.106
Effective Date: 01/18
Last Review Date: 11/16 Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for enzalutamide (Xtandi®) capsules for oral use.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Xtandi is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of metastatic castration-resistant prostate cancer (CRPC) as evidenced by disease progression despite androgen deprivation therapy [e.g., gonadotropin-releasing hormone (GnRH) agonist (e.g., leuprolide, goserelin), GnRH antagonist (e.g., degarelix)];
2. Prescribed dose of Xtandi does not exceed 160 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Prostate Cancer (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies:
2. Prescribed dose of Xtandi does not exceed 160 mg per day;
3. Member has none of the following reasons to discontinue:
   a. Disease progression or unacceptable toxicity;
   b. Development of seizure during treatment;
   c. Posterior reversible encephalopathy syndrome.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background
Description/Mechanism of Action:

Enzalutamide is an androgen receptor inhibitor that acts on different steps in the androgen receptor signaling pathway. Enzalutamide has been shown to competitively inhibit androgen binding to androgen receptors and inhibit androgen receptor nuclear translocation and interaction with DNA. A major metabolite, N-desmethyl enzalutamide, exhibited similar in vitro activity to enzalutamide. Enzalutamide decreased proliferation and induced cell death of prostate cancer cells in vitro, and decreased tumor volume in a mouse prostate cancer xenograft model.

Formulations:
Xtandi is available in 40 mg capsules for oral administration.

FDA Approved Indications:
Xtandi is an androgen receptor inhibitor/oral capsule formulation indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Appendices
Appendix A: Abbreviation Key
CRPC: castration-resistant prostate cancer
GnRH: gonadotropin-releasing hormone
PRES: posterior reversible encephalopathy syndrome

Reviews, Revisions, and Approvals	Date	Approval Date

References
1. Xtandi Prescribing Information. Northbrook, IL: Astellas Pharma US.; October 2015. Available at: https://www.xtandi.com/. Accessed August 8, 2016.
2. Enzalutamide. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed August 8, 2016.