UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xtandi

Program	Prior Authorization
Medication	Xtandi® (enzalutamide)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Xtandi® (enzalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with metastatic castration-resistant prostate cancer.[1] The National Cancer Comprehensive Network (NCCN) also approves the use of Xtandi as a single agent for second-line hormonal therapy for prostate cancer relapse or metastases following medical or surgical androgen deprivation therapy (ADT) as well as in combination with a gonadotropin-releasing hormone (GnRH) agonist as initial androgen deprivation therapy in patients with prostate cancer.[2]

2. Coverage Criteria:

A. Prostate Cancer

1. Initial Authorization

a. **Xtandi** will be approved based on all of the following criteria:

(1) Diagnosis of prostate cancer

-AND-

(2) **One** of the following:

(a) Both of the following:

i. Disease is metastatic, castration-resistant or recurrent

-AND-

ii. **One** of the following:

a. History of failure, contraindication, or intolerance to Zytiga

-OR-

b. Continuation of ongoing Xtandi therapy

-OR-

(b) Xtandi will be utilized in combination with gonadotropin-releasing hormone (GnRH) agonist as initial androgen deprivation therapy (ADT)

Authorization will be issued for 12 months.

2. **Reauthorization Criteria**

a. Xtandi will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Xtandi therapy

Authorization will be issued for 12 months.

3. References:

1. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc. July 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 27, 2017.

Program	Prior Authorization- Xtandi (enzalutamide)
Change Control	
Date	Change
9/2013	New guideline
12/2013	Add requirement of a trial and failure of Zytiga (abiraterone)
12/2015	Added "For continuation of prior Xtandi therapy" to allow for approval of Xtandi without a trial of Zytiga for patients who have already established therapy with Xtandi.
9/2016	Updated clinical criteria to align with Employer and Individual notification policy and updated policy template.
9/2017	Annual review. Updated background and criteria to include NCCN recommendation as initial androgen deprivation therapy for prostate cancer in combination with a GnRH agonist. Updated references. Added step through Zytiga.