UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xtandi

Program	Prior Authorization
Medication	Xtandi® (enzalutamide)
Markets in Scope	Arizona, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, South Carolina, Rhode Island, California
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

1. Background:

Xtandi® (enzalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer.[1]

2. Coverage Criteria:

A. <u>Prostate Cancer</u>

1. <u>Initial Authorization</u>

a. **Xtandi** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of prostate cancer

-AND-

(2) **<u>One</u>** of the following:

(a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

-OR-

(b) Patient has had bilateral orchiectomy

-AND-

(3) **<u>One</u>** of the following:

(a) **<u>Both</u>** of the following:

i. Disease is metastatic, castration-resistant

-AND-

ii. **One** of the following:

(a) History of failure, contraindication, or intolerance to Zytiga

-OR-

(b) Continuation of ongoing Xtandi therapy

-OR-

(b) **Both** of the following:

i. Disease is non-metastatic, castration-resistant

-AND-

ii. **One** of the following:

a. History of failure, contraindication, or intolerance to **both** of the following: Erleada (apalutamide) and Nubeqa (darolutamide)

-OR-

b. Continuation of ongoing Xtandi therapy

-OR-

(c) **Both** of the following:

i. Disease is metastatic, castration-sensitive

-AND-

ii. **One** of the following:

(a) History of failure, contraindication, or intolerance to **both** of the following: Erleada (apalutamide) and Zytiga (abiraterone)

-OR-

(b) Continuation of ongoing Xtandi therapy

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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Xtandi** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Xtandi therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc. December 2019.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 30, 2020.

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.
5/2018	Updated background and criteria to remove for use as initial androgen deprivation therapy since it is no longer recommended by NCCN. Added NCCN recommended regimen review criteria. Updated references.
8/2018	Updated background and criteria to align with new indication in non-metastatic setting. Updated references.
10/2018	Added step requirement through Erleada for non-metastatic disease.
9/2019	Annual review. No changes to clinical criteria. Updated references.
1/2020	Revised step therapy requirement for non-metastatic disease due to PDL changes.
3/2020	Updated background and criteria to include criteria for metastatic castration-sensitive prostate cancer. Updated references.