

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2020 P 3027-13
Program	Step Therapy
Medication	Xtandi <sup>®</sup> (enzalutamide)
P&T Approval Date	8/2013, 10/2013, 11/2014, 11/2015, 9/2016, 8/2017, 12/2017, 10/2018, 10/2019, 1/2020, 3/2020, 5/2020
Effective Date	8/1/2020; Oxford only: 8/1/2020

**1. Background:**

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial of or contraindication to alternative agents before providing coverage for Xtandi<sup>®</sup> (enzalutamide) for the treatment of patients with castration-resistant prostate cancer

Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer.<sup>1</sup>

Zytiga<sup>®</sup> (abiraterone acetate) is a CPY17 inhibitor-indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer and for high-risk metastatic castration-sensitive prostate cancer.<sup>3</sup>

Erleada<sup>®</sup> (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer.<sup>4</sup>

Nubeqa<sup>®</sup> (darolutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.<sup>5</sup>

Members currently on Xtandi therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

## 2. Coverage Criteria <sup>a,b</sup>:

### A. Patients less than 19 years of age

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

- a. Member is less than 19 years of age

**Authorization will be issued for 12 months**

### B. Prostate Cancer

1. **Xtandi** will be approved based on **one** of the following criterion:

- a. **Both** of the following:

(1) Diagnosis of metastatic, castration-resistant prostate cancer

**-AND-**

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

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

**-OR-**

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

- i. As continuation of therapy

**-AND-**

- ii. Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Astellas sponsored Xtandi Support Solutions™ program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Xtandi

**-OR-**

- b. **Both** of the following:

(1) Diagnosis of non-metastatic, castration-resistant prostate cancer

**-AND-**

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

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

**-OR-**

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

- i. As continuation of therapy

**-AND-**

- ii. Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Astellas sponsored Xtandi Support Solutions™ program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Xtandi

**-OR-**

c. **Both** of the following:

- (1) Diagnosis of metastatic, castration-sensitive prostate cancer

**-AND-**

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

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

**-OR-**

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

- i. As continuation of therapy

**-AND-**

- ii. Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Astellas sponsored Xtandi Support Solutions™ program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Xtandi

\*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Astellas sponsored Xtandi Support Solutions™ program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months**

### **C. Other Indications**

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

- a. Diagnoses other than prostate cancer

**Authorization will be issued for 12 months**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

<sup>b</sup> Coverage of oncology medications used to treat stage four advanced metastatic cancer may be approved based on state mandates.

### **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 and/or Notification may be in place.
- Coverage of oncology medications used to treat stage IV advanced metastatic cancer may be approved based on state mandates.

#### 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](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed January 30, 2020.
3. Zytiga [package insert]. Horsham, PA: Janssen Biotech Inc.; June 2019.
4. Erleada [package insert]. Horsham, PA: Janssen Products LP. September 2019.
5. Nubeqa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. July 2019.

Program	Step Therapy - Xtandi (enzalutamide)
<b>Change Control</b>	
8/2013	New step therapy criteria.
10/2013	Added educational statement.
11/2014	Annual review. Added approval time frame. Updated background & references.
11/2015	Annual review. Minor revision to prostate cancer diagnosis and added sample pack language. Updated background & references. Added Maryland Continuation of Care.
7/2016	Added Indiana and West Virginia coverage information.
9/2016	Annual Review. Updated references.
11/2016	Administrative change. Added California coverage information.
8/2017	Updated background to include NCCN recommendations. Updated sample pack verbiage. Updated state mandate verbiage. Added Maryland and Connecticut mandate regarding step therapy/non-formulary/exclusion requirements for agents treating stage IV metastatic cancer.
12/2017	Administrative change. Removed state specific mandate verbiage. General reference to potential state mandated coverage bypass stage IV advanced metastatic cancer
10/2018	Updated background and criteria to include criteria for non-metastatic castration-resistant prostate cancer. Updated references.
10/2019	Annual review with no changes to clinical coverage criteria. Updated references.
1/2020	Revised step therapy requirement for non-metastatic disease. Updated formatting.
3/2020	Updated background and criteria to include criteria for metastatic

	castration-sensitive prostate cancer. Updated references.
5/2020	Updated criteria formatting for clarification without change to clinical intent.