UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1117-13
Program	Prior Authorization/Notification
Medication	Xtandi® (enzalutamide)
P&T Approval Date	11/2012, 7/2013, 8/2013, 11/2014, 11/2015, 9/2016, 9/2017, 5/2018, 8/2018, 9/2019, 3/2020, 3/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Xtandi® (enzalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer (CRPC), metastatic castration-sensitive prostate cancer (mCSPC), and non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR).

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[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. 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) Disease is castration-resistant

         -OR-

(b) Disease is **both** of the following:

i. Metastatic
ii. Castration-sensitive

-OR-

(c) Disease is **all** of the following:

i. Non-metastatic
ii. Castration-sensitive
iii. Recurrent
iv. High risk for metastasis

-AND-

(3) **One** 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

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.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] 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.

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 Step Therapy may be in place.

4. References:

1. Xtandi [package insert]. Northbrook, IL: Astellas Pharma US, Inc. November 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed November 21, 2023.

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Change Control	
11/2014	Annual review. Added 'relapsed' to prostate cancer criteria. Updated background & references.
11/2015	Annual review. Revised prostate cancer criteria. Updated background & references.
9/2016	Annual review. Updated references
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.
5/2018	Updated background and criteria to remove criteria for use as initial androgen deprivation therapy as no longer recommended by NCCN.
8/2018	Updated background and criteria with to align with new indication in non-metastatic setting. Updated criteria to include requirement to use in combination with GnRH analog or bilateral orchiectomy as per label.
9/2019	Annual review with no changes to coverage criteria. Updated reference. Added general NCCN recommended review criteria.
3/2020	Updated background and criteria to include new labeled indication for metastatic castration-sensitive prostate cancer.
3/2021	Annual review. No changes to coverage criteria. Updated references.
3/2022	Annual review. No changes to coverage criteria. Updated references.
3/2023	Annual review with no change to coverage criteria. Updated references. Added state mandate footnote.
3/2024	Annual review. Updated background and criteria with expanded indication in non-metastatic castration-sensitive setting. Updated references.