EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Xtandi® (enzalutamide capsules – Astellas Pharma/Catalent Pharma Solutions/Medivation)

TAC APPROVAL DATE: 02/27/2019

OVERVIEW

Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer (CRPC).[1] Xtandi exhibits its effects as an inhibitor by affecting different steps in the androgen receptor signaling pathway. It competitively inhibits androgen binding to the androgen receptor and also inhibits androgen receptor nuclear translocation and interaction with DNA.

Guidelines

According to the NCCN guidelines on prostate cancer (version 4.2018 – August 15, 2018), all patients with mCRPC should maintain castrate levels of serum testosterone (< 50 ng/dL) and receive best supportive care.[2] Erleada™ (apalutamide tablets) and Xtandi are the category 1 recommended options for non-metastatic CRPC (M0) especially if the prostate specific antigen doubling time (PSADT) ≤ 10 months.

- For patients who progress to CRPC and are positive for distant metastasis, M1, and there are no visceral metastases, Zytiga® (abiraterone acetate tablets) and prednisone, docetaxel, Xtandi, and Xofigo® (radium Ra 223 dichloride injection, for intravenous use) [for symptomatic bone metastases] are all category 1 recommended options.
  - If there are visceral metastases, and if it is adenocarcinoma (majority), Xtandi and docetaxel are category 1 recommended options. Zytiga and prednisone, mitoxantrone with prednisone, or other secondary hormone therapies are other options (all category 2A).
  - For no visceral metastases, if patients had received prior therapy with Xtandi or Zytiga, then docetaxel and Xofigo are the category 1 options for subsequent therapy. If patients received prior docetaxel therapy, then Xtandi, Zytiga, Xofigo, and cabazitaxel are the category 1 options. For subsequent therapy with visceral metastases, docetaxel is the recommended category 1 option, if either Xtandi or Zytiga were used as prior therapies. For prior therapy with docetaxel, Xtandi, Zytiga, cabazitaxel are the recommended category 1 options.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Xtandi. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xtandi is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Prostate Cancer –Castration-Resistant (CRPC) [Metastatic or Non-Metastatic].** Approve for 3 years.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xtandi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xtandi® [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; July 2018.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 4.2018 – August 15, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 25, 2019.
3. Hussain M, Fizazi K, Saad F, et al. Enzalutamide in men with nonmetastatic, castration-resistant prostate cancer. *N Engl J Med.* 2018;378:2465-2474.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	No changes	01/15/2014
Selected revision	Approval duration extended from 1 year to 3 years	09/03/2014
DEU revision	Added new indication for Xtandi and updated NCCN guidelines on 11/4/14. No criteria changes.	N/A
Annual revision	No criteria changes.	2/25/2015
Annual revision	Added new approval condition for patients with non-metastatic castration-resistant prostate cancer.	02/24/2016
Early Annual revision	No criteria changes	02/01/2017
Annual revision	No criteria changes	02/28/2018
Selected revision	Xtandi is now FDA-approved for use in CRPC, regardless of metastatic status. Modified approval condition to match FDA indication. Deleted separate approval for non-metastatic CRPC from Other Uses with Supportive Evidence.	07/25/2018
Annual revision	No criteria changes	02/27/2019

TAC – Therapeutic Assessment Committee; DEU – Drug Evaluation Unit; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx; N/A – Not applicable.