EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Yonsa® (abiraterone acetate tablets – Sun Pharmaceutical Industries, Inc.)

TAC APPROVAL DATE: 05/22/2019

OVERVIEW

Yonsa is an androgen biosynthesis inhibitor that inhibits the enzyme 17 α-hydroxylase/C17,20-lyase (CYP17).[1] This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis. Yonsa, in combination with methylprednisolone, is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). Inhibition of CYP17 by Yonsa can also result in increased mineralocorticoid production by the adrenal glands; the use of methylprednisolone with Yonsa is to counteract this mineralocorticoid excess.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on prostate cancer (version 2.2019 – April 17, 2019) have the following recommendations for Zytiga® [abiraterone acetate tablets] and Yonsa.[2]

- At initial diagnosis, for patients classified in the regional risk group (metastases in regional nodes [N1] with no distant metastases [M0]) and with a > 5 year expected patient survival, external beam radiation therapy (EBRT) + androgen deprivation therapy (ADT) [category 1] + Zytiga and prednisone (category 2A) or Yonsa and methylprednisolone (category 2B) are recommended options. ADT (without EBRT) ± Zytiga and prednisone is a category 2A recommended option in this setting; ADT + Yonsa and methylprednisolone is a category 2B recommendation.
- If patients are positive for distant metastasis (M1) and have castration-naïve disease, ADT + Zytiga and prednisone and ADT + docetaxel are both category 1 recommended options. ADT + Yonsa and methylprednisolone is a category 2B recommendation in this setting.
- For patients who progress to CRPC and are positive for distant metastasis, M1 and there are no visceral metastases, Zytiga and prednisone, docetaxel, Xtandi, and Xofigo® (radium Ra 223 dichloride injection, for intravenous use) [for symptomatic bone metastases] are all category 1 recommended options. Yonsa + methylprednisolone is a category 2A recommendation for mCRPC either as first-line or subsequent therapy option.
  - If there are visceral metastases, Xtandi and docetaxel are category 1 recommended options. Zytiga and prednisone, Yonsa and methylprednisolone are category 2A recommendations for first-line or second-line treatment after Xtandi. If docetaxel was used previously, Zytiga and prednisone is a category 1 recommendation; Yonsa and methylprednisolone is a category 2A recommendation.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Yonsa. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Prostate Cancer – Metastatic, Castration-Resistant (mCRPC).** Approve for 3 years if Yonsa is used in combination with methylprednisolone.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Yonsa 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. Yonsa® tablets [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; May 2018.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 2. 2019 – April 17, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 20, 2019.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New Policy	New criteria	05/23/2018
Annual revision	No criteria changes	05/22/2019

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.