

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Yonsa Prior Authorization Policy

- Yonsa® (abiraterone acetate tablets – Sun Pharmaceutical)

REVIEW DATE: 08/07/2024

OVERVIEW

Yonsa, an androgen biosynthesis inhibitor, is indicated in combination with methylprednisolone for the treatment of patients with **metastatic castration-resistant prostate cancer (CRPC)**.¹

Guidelines

The National Comprehensive Cancer Network guidelines on prostate cancer (version 4.2024 – May 17, 2024) recommend Yonsa for the following uses: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® (abiraterone acetate tablets) 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 with metastatic CRPC and who have not received prior docetaxel or prior novel hormone therapy, Zytiga + prednisone (category 1 without visceral metastases and category 2A with visceral metastases) and Yonsa + methylprednisolone (category 2A) is recommended.
- For patients with metastatic CRPC who have received prior novel hormone therapy but no prior docetaxel, Zytiga + prednisone or Yonsa + methylprednisolone is recommended (category 2A); Zytiga + dexamethasone or Yonsa + dexamethasone is recommended in this setting if patients have had disease progression on either formulation of abiraterone (category 2A). If docetaxel was used previously but no prior hormone therapy, Zytiga + prednisone (category 1) or Yonsa + methylprednisolone (category 2A) is recommended. If docetaxel and prior novel hormone therapy were used, Zytiga + prednisone or Yonsa + methylprednisolone are recommended (category 2A without visceral metastases; category 2B with visceral metastases).
- In metastatic CRPC with *BRCA* mutation positive tumors, Yonsa can be used in combination with Lynparza® (olaparib tablets) [category 2A] or Zejula® (niraparib tablets) [category 2B].

POLICY STATEMENT

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

Automation: None.

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RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Prostate Cancer – Metastatic, Castration-Resistant.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) The medication is used in combination with methylprednisolone or dexamethasone; AND
 - B) Patient meets ONE of the following (i or ii):
 - i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog;
OR
Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
 - ii. Patient has had a bilateral orchiectomy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Yonsa is not recommended in the following situations:

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; March 2022.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 5, 2024.