

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Yonsa Prior Authorization Policy

- Yonsa® (abiraterone acetate tablets – Sun Pharmaceutical)

REVIEW DATE: 07/27/2022

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 4.2022 – May 10, 2022) 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).

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 the following criteria (A and B):
 - A)** The medication is used in combination with methylprednisolone or dexamethasone; **AND**
 - B)** Patient meets **ONE** of the following criteria (i, ii, or iii):
 - i.** The medication is concurrently used with a gonadotropin-releasing hormone agonist; **OR**
Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), or Vantas (histrelin acetate subcutaneous implant).
 - ii.** The medication is concurrently used with Firmagon (degarelix subcutaneous injection); **OR**
 - iii.** 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; June 2021.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – May 10, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 26, 2022.