Prior Authorization
Oncology – Yonsa® (abiraterone acetate tablets)

Table of Contents

Product Identifier(s)

60467

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National Formulary Medical Necessity

Cigna covers abiraterone acetate (Yonsa®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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

FDA Indication(s)

1. **Prostate Cancer – Metastatic, Castration-Resistant.** Approve for 1 year if the individual meets the following criteria (A and B):
   - **A)** The medication is used in combination with methylprednisolone or dexamethasone; AND
   - **B)** Individual 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. Individual has had a bilateral orchiectomy.

Conditions Not Covered

Abiraterone acetate (Yonsa®) is considered experimental, investigational or unproven for ANY other use.

Background

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).

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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes. **Prostate Cancer:** Orgovyx was added as an example of gonadotropin-releasing hormone analog.	07/21/2021
Selected Revision	**Prostate Cancer – Metastatic, Castration-Resistant:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Annual Revision	**Prostate Cancer – Metastatic, Castration-Resistant**: Dexamethasone was also added as an option to the criteria requiring combination use with methylprednisolone. The criterion requiring trial of gonadotropin-releasing hormone "analog" was revised to	07/27/2022

	"agonist". An option that the medication is used in combination with Firmagon (degarelix subcutaneous injection) was added.	