UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 1273-5 |
| Program | Prior Authorization/Notification |
| Medication | Yonsa® (abiraterone acetate)*<br><br>*Yonsa is excluded from coverage for the majority of our benefits |
| P&T Approval Date | 2/2019, 2/2020, 2/2021, 2/2022, 2/2023 |
| Effective Date | 5/1/2023;<br>Oxford only: 5/1/2023 |

**1. Background:**

Yonsa® (abiraterone acetate)* is a CPY17 inhibitor indicated for use in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Yonsa* or should have had bilateral orchiectomy.[1] The National Comprehensive Cancer Network (NCCN) also recommends the use of Yonsa* in combination with methylprednisolone and androgen deprivation therapy as initial therapy for patients with metastatic castration-naïve disease or in patients without metastases yet with regional node positive disease and the use of Yonsa* in combination with androgen deprivation therapy and external bean radiation therapy (EBRT) as initial therapy in patients with very-high-risk, node negative prostate cancer. [2]

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria[a]:**

**A. <u>Patients less than 19 years of age</u>**

1. **Yonsa*** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   **Authorization will be issued for 12 months.**

**B. <u>Initial Authorization</u>**

1. **Yonsa*** will be approved based on **<u>all</u>** of the following criteria:

   a. Diagnosis of prostate cancer

   **-AND-**

   b. **<u>One</u>** of the following:

(1) Disease is metastatic

**-OR-**

(2) Disease is regional node positive (e.g., N1)

**-OR-**

(3) Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT)

**-AND-**

c. Used in combination with methylprednisolone

**-AND-**

d. **One** of the following:

(1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Firmagon (degarelix)]

**-OR-**

(2) Patient has had bilateral orchiectomy

**Authorization will be issued for 12 months.**

**C. Reauthorization**

1. **Yonsa*** will be approved based on the following criterion:

a. Patient does not show evidence of progressive disease while on Yonsa* therapy

**Authorization will be issued for 12 months.**

**D. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Step Therapy may be in place.
- *Exclusion: Yonsa is excluded from coverage for the majority of our benefits

**4. References:**

1. Yonsa [package insert]. Cranbury, NJ: Sun Pharma Global FZE; March 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed December 23, 2022.

| Program | Prior Authorization/Notification - Yonsa (abiraterone acetate) |
|---|---|
| **Change Control** | |
| 2/2019 | New program |
| 2/2020 | Annual review. Added general NCCN recommendations for use criteria. Updated references. |
| 2/2021 | Annual review. Added patient has not shown progression of disease while on another formulation of abiraterone to coverage criteria per NCCN recommendations. Updated references. |
| 2/2022 | Annual review. Added criteria for use in combination with EBRT in very-high-risk groups and removed patient has not shown progression of disease while on another formulation per NCCN recommendations. Updated references. |
| 2/2023 | Annual review. Updated examples of GnRH analogs to remove discontinued product Vantas. Added state mandate and updated references. |