UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1273-6
Program	Prior Authorization/Notification
Medication	Yonsa® (abiraterone acetate)* *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, 2/2024
Effective Date	5/1/2024

1. Background:

Yonsa® (abiraterone acetate)* is a CYP 17 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 (ADT) as initial therapy for patients with metastatic or regional node positive prostate cancer, or in combination with ADT and external bean radiation therapy (EBRT) as initial therapy in patients with very-high-risk, node negative prostate cancer. Yonsa* is also recommended in combination with methylprednisolone and ADT for M0 prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy in combination with external beam radiation therapy (EBRT) if studies are positive for pelvic recurrence and life expectancy > 5 years, or for treatment of castration-resistant distant metastatic (M1) disease as secondary hormone therapy or in certain circumstances in combination with methylprednisolone, ADT, and either niraparib or olaparib.[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. **One** 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 26, 2023.

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.
2/2024	Annual review. Updated background.