



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3120-7
Program	Step Therapy
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, 4/2022, 2/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try another formulation of abiraterone acetate, Zytiga[™], before providing coverage for Yonsa^{®*} for the treatment of prostate cancer.

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.

Zytiga (abiraterone acetate) is a CYP 17 inhibitor indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer and for high-risk metastatic castration-sensitive prostate cancer.

Members currently on Yonsa* therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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,b}:

<p>A. <u>Patients less than 19 years of age</u></p> <p>1. Yonsa* will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. Member is less than 19 years of age</p> <p style="text-align: center;">Authorization will be issued for 12 months</p> <p>B. <u>Prostate Cancer</u></p> <p>1. Yonsa* will be approved based on all of the following criterion:</p>

a. Yonsa* is to be used in combination with methylprednisolone

-AND-

b. **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

-AND-

c. **One** of the following:

- (1) Patient has a contraindication, or history of intolerance to Zytiga (abiraterone acetate)

-OR-

- (2) Provider attests that the patient is not an appropriate candidate for Zytiga (abiraterone acetate)

-OR-

(3) **Both** of the following:

- (a) As continuation of therapy

-AND-

- (b) Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from a Sun Pharma sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30-day free trial from a pharmacy as a means to establish as a current user of Yonsa*

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Sun Pharma sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months

C. Other Indications

1. **Yonsa*** will be approved

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.

^b Coverage of oncology medications may be approved based on state mandates.

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 and/or Notification may be in place.
- *Exclusion: Yonsa is excluded from coverage for the majority of our benefits
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. Yonsa [package insert]. Cranbury, NJ: Sun PharmaGlobal FZE; July 2022.
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.
3. Zytiga [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2021.

Program	Step Therapy - Yonsa (abiraterone acetate)
Change Control	
2/2019	New program
2/2020	Annual review with no changes to clinical coverage 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. Removed patient has not shown progression of disease while on another formulation per NCCN recommendations. Updated references.
4/2022	Updated oncology medications state mandate note.
2/2023	Annual review. Updated examples of GnRH analogs to remove discontinued product Vantas. Updated references.
2/2024	Annual review. No changes to step therapy criteria. Updated reference.