

### Clinical Pharmacy Program Guidelines for Yonsa

Program	Prior Authorization
Medication	Yonsa <sup>®</sup> (abiraterone)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania- CHIP, South Carolina, Rhode Island
Issue Date	1/2019
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

#### 1. Background:

Yonsa (abiraterone) is a CYP17 inhibitor indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC). Patients receiving Yonsa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. 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.

#### 2. Coverage Criteria:

<p><b>A. <u>Prostate Cancer</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p><b>a. Yonsa</b> will be approved based on <b><u>all</u></b> of the following criteria:</p> <p>(1) Diagnosis of prostate cancer</p> <p style="text-align: center;"><b>-AND-</b></p> <p>(2) <b><u>One</u></b> of the following:</p> <p>(a) Disease is metastatic</p> <p style="text-align: center;"><b>-OR-</b></p> <p>(b) Disease is regional node positive (e.g., N1)</p>
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**-AND-**

(3) Used in combination with methylprednisolone

**-AND-**

(4) **One** of the following:

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

**-OR-**

(b) Patient has had bilateral orchiectomy

**-AND-**

(5) Patient has not shown progression of disease while on another formulation of abiraterone [e.g. Zytiga (abiraterone)]

**-AND-**

(6) **One** of the following:

(a) Prescriber provides a reason or special circumstance the patient cannot take Zytiga

**-OR-**

(b) Patient is currently on Yonsa therapy

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

## **2. Reauthorization**

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

(1) Patient does not show evidence of progressive disease while on Yonsa therapy

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

## **B. NCCN Recommended Regimens**

<p><b>1. <u>Initial Authorization</u></b></p> <p>a. <b>Yonsa</b> will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.</p> <p><b>Authorization will be issued for 12 months.</b></p> <p><b>2. <u>Reauthorization</u></b></p> <p>a. <b>Yonsa</b> will be approved based on the following criterion:</p> <p>(1) Documentation of positive clinical response to Yonsa therapy</p> <p><b>Authorization will be issued for 12 months.</b></p>
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**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

**4. References:**

1. Zytiga [package insert]. Horsham, PA: Janssen Biotech Inc.; October 2020.
2. Yonsa [package insert]. Cranbury, NJ: Sun Pharma Global FZE; August 2020.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed December 14, 2020.

Program	Prior Authorization
<b>Change Control</b>	
Date	Change
1/2019	New program
1/2020	Annual review. Updated background and references.
1/2021	Annual review. Updated references. Added Additional Clinical Rules section.
2/2021	Added patient has not shown progression of disease while on another formulation of abiraterone to coverage criteria per NCCN recommendations. Updated references

