

## DRUG QUANTITY MANAGEMENT POLICY – PER RX

**POLICY:** Oncology – Abiraterone Acetate Drug Quantity Management Policy – Per Rx

- Yonsa® (abiraterone acetate tablets – Sun Pharmaceutical Industries)
- Zytiga® (abiraterone acetate tablets – Janssen Biotech, generic)

**REVIEW DATE:** 05/25/2022; selected revision 06/15/2022

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### OVERVIEW

The abiraterone acetate products are 17  $\alpha$ -hydroxylase/C17, 20-lyase (CYP17) inhibitors.<sup>1,2</sup>

Yonsa is indicated in combination with methylprednisolone for the treatment of patients with **metastatic castration-resistant prostate cancer (CRPC)**.<sup>1</sup>

Abiraterone acetate (Zytiga, generic) is indicated for the treatment of patients with:<sup>2</sup>

- **Metastatic CRPC**
- **Metastatic high-risk castration-sensitive prostate cancer (CSPC)**

### Dosing

#### *Yonsa*

The recommended dose of Yonsa is 500 mg (four 125 mg tablets) administered orally once daily (QD) in combination with methylprednisolone 4 mg administered orally twice daily (BID).<sup>1</sup> Yonsa can be taken with or without food. Tablets should not be crushed or chewed.

The Yonsa dose should be reduced in patients with hepatic impairment (Child-Pugh Class B) or hepatotoxicity.<sup>1</sup> Use of Yonsa with strong cytochrome P450 (CYP)3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital) should be avoided. However, if a strong CYP3A4 inducer must be co-administered, increase the dosing frequency of Yonsa to BID (e.g., from 500 mg QD to 500 mg BID). Once the concomitant strong CYP3A4 inducer is discontinued, reduce the dose back to the previous frequency.

#### *Abiraterone Acetate (Zytiga, generic)*

For metastatic CRPC, the recommended dose of abiraterone acetate is 1,000 mg QD with prednisone 5 mg BID.<sup>2</sup> The recommended dose is also 1,000 mg QD for metastatic CSPC, but in this setting it is given with 5 mg of prednisone QD. Patients who are taking abiraterone acetate should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. Abiraterone acetate is given as a single dose QD on an empty stomach. Tablets should not be chewed or crushed.

For patients with baseline moderate hepatic impairment, the recommended starting dose of abiraterone acetate is 250 mg QD.<sup>2</sup> If a patient develops hepatotoxicity during treatment, hold abiraterone acetate until recovery and then resume at a reduced dose. If severe hepatotoxicity develops, discontinue abiraterone acetate. Use of abiraterone acetate with strong CYP3A4 inducers (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital) should be avoided. However, if a strong CYP3A4 inducer must be co-administered, increase the dosing frequency of abiraterone acetate to BID (e.g., from 1,000 mg QD to 1,000 mg BID). Once the concomitant strong CYP3A4 inducer is discontinued, reduce the dose back to the previous frequency.

### Availability

05/25/2022

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Yonsa is available as 125 mg tablets in bottles containing 120 tablets each.<sup>1</sup>

Abiraterone acetate (Zytiga, generic) is available as 250 mg (120 tablets per bottle) and 500 mg tablets (60 tablets per bottle).<sup>2</sup>

### **POLICY STATEMENT**

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Yonsa and abiraterone acetate (Zytiga, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

**Automation:** None.

### **Drug Quantity Limits**

<b>Product</b>	<b>Package Size</b>	<b>Maximum Quantity per Rx</b>
Yonsa <sup>®</sup> (abiraterone acetate tablets)	125 mg tablets	120 tablets
Zytiga <sup>®</sup> (abiraterone acetate tablets, generic)	250 mg tablets	120 tablets
	500 mg tablets	60 tablets

### **CRITERIA**

#### Yonsa 125 mg tablets

1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer, approve 240 tablets per dispensing.

Note: Strong CYP3A4 inducers include, but are not limited to, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital.

#### Abiraterone acetate 250 mg tablets (Zytiga, generic)

No overrides recommended.

#### Abiraterone acetate 500 mg tablets (Zytiga, generic)

1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer, approve 120 tablets per dispensing.

Note: Strong CYP3A4 inducers include, but are not limited to, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital.

### **REFERENCES**

1. Yonsa<sup>®</sup> tablets [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; June 2021.
2. Zytiga<sup>®</sup> tablets [prescribing information]. Horsham, PA: Janssen; August 2021.

