

## Abiraterone acetate (Zytiga™, Yonsa®) (Oral)

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Dates Reviewed: 12/2012, 11/2013, 06/2014, 06/2015, 04/2017, 03/2018, 06/2018

### I. Length of Authorization

Coverage is provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Zytiga 250 mg tablets: 4 tablets per day
- Zytiga 500 mg tablets: 2 tablets per day
- Yonsa 125 mg tablets: 4 tablets per day

#### B. Max Units (per dose and over time) [Medical Benefit]:

- Zytiga: 1,000 mg daily
- Yonsa: 500 mg daily

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient age 18 years and older; **AND**
- Patient will receive a GnRH-analog or has had a bilateral orchiectomy; **AND**

#### Prostate Cancer †

- Patient has metastatic disease that is castration-resistant; **AND**
  - Used in combination with prednisone or methylprednisolone; **OR**
- Initial therapy for disease without visceral metastases and for progression if previously treated with a docetaxel-based regimen (*Zytiga only*); **OR**
- Patient has metastatic disease that is castration sensitive (*Zytiga only*); **AND**
  - Patient has high-risk disease (defined as defined as having at least two of three risk factors at baseline: a total Gleason score of  $\geq 8$ , presence of  $\geq 3$  lesions on bone scan, and evidence of measurable visceral metastases); **AND**
  - Patient is newly diagnosed and treatment-naive

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: uncontrolled hypertension; hypokalemia; hepatotoxicity, severe adrenocortical insufficiency, etc.

#### V. Dosage/Administration

Indication	Dose
Prostate Cancer	<b>Zytiga</b>
	<u>Castration-Resistant Disease</u> <ul style="list-style-type: none"><li>– 1,000 mg by mouth daily on an empty stomach in combination with prednisone 5 mg twice daily</li></ul>
	<u>Castration-Sensitive Disease</u> <ul style="list-style-type: none"><li>– 1,000 mg by mouth daily on an empty stomach in combination with prednisone 5 mg once daily</li></ul>
	<b>Yonsa</b>
	<u>Castration-Resistant Disease</u> <ul style="list-style-type: none"><li>– 500 mg (four 125 mg tablets) by mouth daily with or without food in combination with methylprednisolone 4 mg orally twice daily</li></ul>
<i>Note: Patients receiving Zytiga and Yonsa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.</i>	

#### VI. Billing Code/Availability Information

HCPCS code:

- J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
- C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use ONLY*)

NDC:

- Zytiga 250 mg uncoated tablet: 57894-0150-xx
- Zytiga 250 mg film-coated tablet: 57894-0184-xx
- Zytiga 500 mg film-coated tablet: 57894-0195-xx
- Yonsa 125 mg tablet: 47335-0401-xx

## VII. References

1. Zytiga [package insert]. Horsham, PA; Janssen Biotech, Inc; Mar 2018. Accessed May 2018.
2. Yonsa [package insert]. Princeton, NJ; Sun Pharmaceuticals; May 2018. Accessed May 2018
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for abiraterone. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to [www.nccn.org/](http://www.nccn.org/). Accessed May 2018.

### Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

### Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC