

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

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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**
- Patient has not progressed following previous receipt of an abiraterone/corticosteroid regimen; **AND**
- Used in combination with prednisone or methylprednisolone (see dosing); **AND**
- Patient must have an intolerance to generic abiraterone 250 mg (see dosing) prior to consideration of another product; **AND**

Prostate Cancer †

- Patient is in the regional risk group (i.e., Any T, N1, M0) with a life expectancy of at least 5 years or is symptomatic ‡; **OR**
- Patient has castration-sensitive metastatic disease (*Zytiga only*) †; **AND**

- Patient has high-risk disease (defined as having at least two of three risk factors at baseline: a total Gleason score of ≥ 8 , presence of ≥ 3 lesions on bone scan, and evidence of measurable visceral metastases); **AND**
- Patient is newly diagnosed and treatment-naïve; **OR**
- Patient has castration-resistant metastatic disease †

† 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	Zytiga
	<u>Castration-Resistant Disease</u> (in combination with prednisone 5 mg twice daily) <ul style="list-style-type: none"> – 250 mg once daily, with food; OR – 1,000 mg by mouth daily on an empty stomach (if lower dosing is not feasible)
	<u>Castration-Sensitive Disease</u> (in combination with prednisone 5 mg once daily) <ul style="list-style-type: none"> – 1,000 mg by mouth daily on an empty stomach
	Yonsa
	<u>Castration-Resistant Disease</u> (in combination with methylprednisolone 4 mg twice daily) <ul style="list-style-type: none"> – 500 mg (four 125 mg tablets) by mouth daily with or without food
<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 500 mg film-coated tablet: 57894-0195-xx

- Yonsa 125 mg tablet: 47335-0401-xx

*generically available

VII. References

1. Zytiga [package insert]. Horsham, PA; Janssen Biotech, Inc; April 2018. Accessed March 2019.
2. Yonsa [package insert]. Princeton, NJ; Sun Pharmaceuticals; May 2018. Accessed March 2019
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/. Accessed April 2019.
4. Szmulewitz RZ, Peer CJ, Ibraheem A, et al. Prospective International Randomized Phase II Study of Low-Dose Abiraterone With Food Versus Standard Dose Abiraterone In Castration-Resistant Prostate Cancer. J Clin Oncol. 2018 May 10;36(14):1389-1395.

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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
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