

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) [NDC Unit]:

- Zytiga 250 mg tablets: 1 tablet 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) [HCPCS Unit]:

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

III. Initial Approval Criteria ¹⁻⁷

Coverage is provided in the following conditions:

- Patient age 18 years and older; **AND**

Universal Criteria

- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Used in combination with prednisone or methylprednisolone (see dosing); **AND**
- Patient must have an intolerance to generic abiraterone 250 mg prior to consideration of another product (*****NOTE:** Applies to both initiation of therapy and continuation of therapy in patients already being treated with a brand name product.); **AND**

Prostate Cancer †

- Patient has not progressed following previous receipt of an abiraterone-corticosteroid regimen; **AND**

- Used as initial therapy for patients in the regional risk group (i.e., Any T, N1, M0) with a life expectancy of >5 years or is symptomatic (*Zytiga only*) ‡; **OR**
- Patient has castration-sensitive/castration-naive metastatic disease (*Zytiga only*) †; **AND**
 - Patient has high-risk disease with at least 2 of the following at baseline:
 - Total Gleason score of ≥8;
 - Presence of ≥3 lesions on bone scan;
 - Evidence of measurable visceral metastases; **OR**
- Patient has castration-resistant metastatic disease (*Zytiga or Yonsa*) †

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

IV. Renewal Criteria ¹⁻⁷

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment defined by 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: uncontrolled hypertension, hypokalemia, fluid retention, hepatotoxicity, severe adrenocortical insufficiency, etc.

V. Dosage/Administration ^{1,2,4}

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/Castration-Naive 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 once daily with or without food

VI. Billing Code/Availability Information

HCPCS code:

– J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

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; June 2019. Accessed April 2020.
2. Yonsa [package insert]. Princeton, NJ; Sun Pharmaceuticals; May 2018. Accessed April 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for abiraterone. National Comprehensive Cancer Network, 2020. 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 2020.
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.
5. Harland S, Staffurth J, Molina A, et al. Effect of abiraterone acetate treatment on the quality of life of patients with metastatic castration-resistant prostate cancer after failure of docetaxel chemotherapy. *Eur J Cancer*. 2013 Nov;49(17):3648-57. doi: 10.1016/j.ejca.2013.07.144. Epub 2013 Aug 22
6. Ryan CJ, Smith MR, Fizazi K, et al. Abiraterone acetate plus prednisone versus placebo plus prednisone in chemotherapy-naive men with metastatic castration-resistant prostate cancer (COU-AA-302): final overall survival analysis of a randomised, double-blind, placebo-controlled phase 3 study. *Lancet Oncol*. 2015 Feb;16(2):152-60. doi: 10.1016/S1470-2045(14)71205-7. Epub 2015 Jan 16
7. Fizazi K, Tran N, Fein L, et al. Abiraterone acetate plus prednisone in patients with newly diagnosed high-risk metastatic castration-sensitive prostate cancer (LATITUDE): final overall survival analysis of a randomised, double-blind, phase 3 trial. *Lancet Oncol*. 2019 May;20(5):686-700. doi: 10.1016/S1470-2045(19)30082-8. Epub 2019 Apr 12
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer 1.2020. National Comprehensive Cancer Network, 2020. 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 Guidelines, go online to NCCN.org. Accessed April 2020.

9. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for abiraterone (fine-particle). National Comprehensive Cancer Network, 2020. 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 2020.

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA): 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
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC