Evolent Clinical Guideline 3191 for Abirtega/Yonsa/Zytiga™ (abiraterone acetate)

Guideline Number:	Applicable Codes	
Evolent_CG_3191		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. *© 2012 - 2026 Evolent. All rights Reserved.*		
Original Date:	**Last Revised Date:**	**Implementation Date:**
February 2012	July 2026	July 2026

TABLE OF CONTENTS

STATEMENT **2**
PURPOSE 2
INDICATIONS **2**
PROSTATE CANCER 2
CONTRAINDICATIONS/WARNINGS **3**
EXCLUSION CRITERIA **3**
CODING AND STANDARDS **4**
CODES 4
APPLICABLE LINES OF BUSINESS 4
POLICY HISTORY **5**
LEGAL AND COMPLIANCE **5**
GUIDELINE APPROVAL 5
Committee *5*
DISCLAIMER 5
REFERENCES **6**

STATEMENT

Purpose

To define and describe the accepted indications for Abirtega/Yonsa/Zytiga (abiraterone acetate) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Prostate Cancer

- Abiraterone + corticosteroid + ADT (Androgen Deprivation Therapy) may be used in members with ANY of the following clinical situations:
    - High Risk localized/non-metastatic prostate cancer (High Risk determination left to member's clinician)
    - Metastatic castrate sensitive prostate cancer
    - Metastatic castrate resistant prostate cancer
    - Non-metastatic castrate resistant prostate cancer (defined by a rising PSA level with or without PSA doubling times of less than 10 months, in members with a baseline PSA greater than 2 ng/ml and castrate levels of testosterone is less than 50 ng/dl).
- NOTE: Per Evolent policy, brand Abirtega/Yonsa/Zytiga are not approvable for prostate cancer. Brand Abirtega/Yonsa/Zytiga would be approvable for use in prostate cancer if the member has an intolerance/contraindication to generic abiraterone. This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) to show that generic abiraterone (at any dose) is inferior to brand Abirtega/Yonsa/Zytiga. Please refer to NCH alternative agents/regimens recommended

by NCH, including but not limited to regimens available at **Evolent Pathways**.

- Abiraterone with olaparib (Lynparza) and prednisone (or prednisolone) may be used for adult members with deleterious or suspected deleterious BRCA-mutated (*BRCAm*) metastatic castration-resistant prostate cancer (mCRPC).
- Abiraterone with niraparib (Zejula) and prednisone may be used for adult members with deleterious or suspected deleterious BRCA-mutated (*BRCAm*) metastatic castration-resistant prostate cancer (mCRPC).
- Abiraterone may be used in combination with Truqap (capivasertib) and prednisone for the treatment of adult members with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test.

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Member has disease progression while taking abiraterone or has not had a trial of generic abiraterone first prior to using brand Abirtega, Yonsa, or Zytiga.
- Dosing exceeds single dose limit and daily maximum dose of Abirtega/Zytiga (abiraterone acetate) 1000 mg or Yonsa (abiraterone acetate) 500 mg.
- Treatment exceeds the maximum limit of Abirtega (abiraterone acetate) 120 (250 mg) tablets/month, Zytiga (abiraterone acetate) 120 (250 mg) or 60 (500 mg) tablets/month, or Yonsa (abiraterone acetate)120 (125 mg) tablets/month.
- Investigational use of Abirtega/Yonsa/Zytiga (abiraterone acetate) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in

some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).

- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J8999 - abiraterone acetate

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
July 2026	• Updated indication section • Updated references
October 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1208 Zytiga or Yonsa (abiraterone acetate) • Added brand name “Abirtega” to relevant sections • Updated indication section • Updated exclusion criteria • Updated maximum dosage form quantities in exclusion criteria • Updated references
October 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Fizazi K, et al; CAPItello-281 Study Group. Capivasertib plus abiraterone in PTEN-deficient metastatic hormone-sensitive prostate cancer: CAPItello-281 phase III study. *Ann Oncol*. 2026 Jan;37(1):53-68. doi: 10.1016/j.annonc.2025.10.004.
2. James ND, et al; STAMPEDE Investigators. Abiraterone for Prostate Cancer Not Previously Treated with Hormone Therapy. *N Engl J Med*. 2017 Jul 27;377(4):338-351. doi: 10.1056/NEJMoa1702900.
3. Ryan CJ, et al. The IMAAGEN Study: Effect of Abiraterone Acetate and Prednisone on Prostate Specific Antigen and Radiographic Disease Progression in Patients with Nonmetastatic Castration Resistant Prostate Cancer. *J Urol*. 2018 Aug;200(2):344-352. doi: 10.1016/j.juro.2018.03.125.
4. Marar M, et al. Outcomes Among African American and Non-Hispanic White Men with Metastatic Castration-Resistant Prostate Cancer with First-Line Abiraterone. *JAMA Netw Open*. 2022 Jan 4;5(1):e2142093. doi: 10.1001/jamanetworkopen.2021.42093.
5. Clarke NW, et al. Abiraterone and Olaparib for Metastatic Castration-Resistant Prostate Cancer. *NEJM Evid*. 2022 Sep;1(9):EVIDoa2200043. doi: 10.1056/EVIDoa2200043.
6. Chi KN, et.al. MAGNITUDE Principal Investigators. Niraparib and Abiraterone Acetate for Metastatic Castration-Resistant Prostate Cancer. *J Clin Oncol*. 2023 Jun 20;41(18):3339-3351. doi: 10.1200/JCO.22.01649.
7. Kluetz PG, et al. Abiraterone acetate in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer: U.S. Food and Drug Administration drug approval summary. *Clin Cancer Res*. 2013 Dec 15;19(24):6650-6. doi: 10.1158/1078-0432.CCR-13-2134.
8. Ryan CJ, et al; COU-AA-302 Investigators. Abiraterone in metastatic prostate cancer without previous chemotherapy. *N Engl J Med*. 2013 Jan 10;368(2):138-48. doi: 10.1056/NEJMoa1209096.
9. Fizazi K, et al; LATITUDE Investigators. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *N Engl J Med*. 2017 Jul 27;377(4):352-360. doi: 10.1056/NEJMoa1704174.
10. Khalaf DJ, et al. Optimal sequencing of enzalutamide and abiraterone acetate plus prednisone in metastatic castration-resistant prostate cancer: a multicentre, randomised, open-label, phase 2, crossover trial. *Lancet Oncol*. 2019 Dec;20(12):1730-1739. doi: 10.1016/S1470-2045(19)30688-6.
11. Abirtega prescribing information. Hikma Pharmaceuticals USA Inc. Berkeley Heights, NJ 2025
12. Zytiga prescribing information. Janssen Biotech, Inc. Horsham, PA 2024.
13. Yonsa prescribing information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ 2022.
14. Clinical Pharmacology Elsevier Gold Standard 2026.
15. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2026.
16. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2026.
17. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2026.
18. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
19. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf**.

20. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: **http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm**.