Evolent Clinical Guideline 3187 for Jevtana™ (cabazitaxel)

Guideline Number:	Applicable Codes	
Evolent_CG_3187		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. *© 2012 - 2025 Evolent. All rights Reserved.*		
Original Date:	**Last Revised Date:**	**Implementation Date:**
October 2012	September 2025	September 2025

TABLE OF CONTENTS

STATEMENT

Purpose

To define and describe the accepted indications for Jevtana (cabazitaxel) 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

- The member has a diagnosis of castration-resistant distant metastatic (M1) disease and has experienced disease progression on docetaxel therapy AND
- Jevtana (cabazitaxel) will be used in combination with a steroid + LHRH analog/orchiectomy as a form of androgen deprivation therapy (ADT).

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Severe hypersensitivity to cabazitaxel or any component of the formulation, or to other medications formulated with polysorbate 80
  - Neutrophil count ≤1,500/mm^3
  - Severe hepatic impairment (total bilirubin >3 times × ULN).
- US Boxed Warning
  - Neutropenic deaths have been reported. Monitor for neutropenia with frequent blood cell counts. Cabazitaxel is contraindicated in patients with neutrophil counts of ≤1,500 cells/mm^3. Primary prophylaxis with G-CSF is recommended in patients with high-risk clinical features. Consider primary prophylaxis with G-CSF in all

patients receiving a dose of 25 mg/m^2.

- Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension, and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the cabazitaxel infusion and administration of appropriate therapy. Patients should receive premedication. Cabazitaxel is contraindicated in patients who have a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80.

EXCLUSION CRITERIA

- Disease progression while on Jevtana (cabazitaxel).
- Dosing exceeds single dose limit of Jevtana (cabazitaxel) 20 mg/m^2
- Investigational use of Jevtana (cabazitaxel) 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 definition 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, in light of 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

- J9043 - Injection, cabazitaxel, 1 mg
- J9064 - Injection, cabazitaxel (sandoz), not therapeutically equivalent to j9043, 1 mg

Applicable Lines of Business

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

POLICY HISTORY

Date	Summary
September 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1219 Jevtana (cabazitaxel) • Added new HCPC code • Updated references
November 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty 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. Matsuyama H, et al. Real-world efficacy and safety of two doses of cabazitaxel (20 or 25 mg/m2) in patients with castration-resistant prostate cancer: results of a Japanese post-marketing surveillance study. *BMC Cancer*. 2020 Jul 13;20(1):649. doi: 10.1186/s12885-020-07131-6.
2. de Bono JS, et al; TROPIC Investigators. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. *Lancet*. 2010 Oct 2;376(9747):1147-54. doi: 10.1016/S0140-6736(10)61389-X.
3. de Wit R, et al; CARD Investigators. Cabazitaxel versus Abiraterone or Enzalutamide in Metastatic Prostate Cancer. *N Engl J Med*. 2019 Dec 26;381(26):2506-2518. doi: 10.1056/NEJMoa1911206.
4. Eisenberger M, et al. Phase III Study Comparing a Reduced Dose of Cabazitaxel (20 mg/m^2) and the Currently Approved Dose (25 mg/m^2) in Postdocetaxel Patients With Metastatic Castration-Resistant Prostate Cancer-PROSELICA. *J Clin Oncol*. 2017 Oct 1;35(28):3198-3206. doi: 10.1200/JCO.2016.72.1076.
5. Jevtana prescribing information. Sanofi-Aventis U.S. LLC. Morristown, NJ 2025.
6. Clinical Pharmacology Elsevier Gold Standard 2025.
7. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2025.
8. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.
9. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.
10. 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.
11. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf**.
12. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: **http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm**.