

Jevtana® (cabazitaxel) (Intravenous)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Jevtana 60 mg solution for injection: 1 vial per 21 day supply

B. Max Units (per dose and over time) [HCPCS Unit]:

- 60 billable units per 21 days

III. Initial Approval Criteria ^{1,2,3}

Coverage is provided in the following conditions:

Universal Criteria

- Must be used in combination with a steroid (e.g. prednisone or dexamethasone); **AND**
- May not be used with other chemotherapy agents

Prostate Cancer †

- Patient is 18 years or older; **AND**
- Patient has castration-resistant metastatic disease; **AND**
- Patient must have been previously treated with docetaxel unless contraindicated or intolerant to docetaxel; **AND**

† FDA Approved Indication(s)

IV. Renewal Criteria ¹

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 as defined by lack of disease progression, improvement in tumor size and/or improvement in patient symptoms; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: neutropenia, anemia, leukopenia, thrombocytopenia, severe hypersensitivity reactions, severe diarrhea, nausea, vomiting, severe hemorrhagic cystitis, renal or hepatic toxicity, interstitial lung disorders, etc.

V. Dosage/Administration

Indication	Dose
Prostate Cancer	Administer 20-25 mg/m ² , intravenously, every 3 weeks in combination with an oral corticosteroid

VI. Billing Code/Availability Information

HCPCS code:

J9043 – Injection, cabazitaxel, 1 mg: 1 billable unit= 1 mg

NDC:

Jevtana 60 mg solution for injection, single-dose vial: 00024-5824-xx

VII. References

1. Jevtana [package insert]. Bridgewater, NJ; Sanofi-Aventis U.S. LLC; January 2018. Accessed February 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cabazitaxel. 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 NCCN.org. Accessed February 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 1.2020. 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 NCCN.org. Accessed February 2020.
4. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. J Oncol Pract. 2018 Mar;14(3):e130-e136.

5. De Bono JS, Oudard S, Ozguroglu M, et al. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomized open-label trial. *Lancet* 2010;376:1145-1154. NCT00417079.
6. Sartor AO, Oudard S, Sengelov L, et al. Cabazitaxel vs docetaxel in chemotherapy-naive (CN) patients with metastatic castration-resistant prostate cancer (mCRPC): A three-arm phase III study (FIRSTANA). *Journal of Clinical Oncology* 34, no. 15_suppl (May 20, 2016):5006-5006. DOI: 10.1200/JCO.2016.34.15_suppl.5006.
7. CGS Administrators, Inc. Local Coverage Article (LCA): Billing and Coding: Cabazitaxel; JEVTANA -J9043 (A56893). Centers for Medicare & Medicare Services. Updated on 09/24/2019 with effective dates 10/03/2019. Accessed March 2020.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	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):

Jurisdiction(s): 15	NCD/LCD Document (s): A56893
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56893&bc=gAAAAAAAAAAAA	

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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