Jevtana® (cabazitaxel)
(Intravenous)

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I. Length of Authorization

Coverage will be provided for 6 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 21day supply

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

– 60 billable units per 21 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1-3]

- Must be used in combination with a steroid (e.g. prednisone or dexamethasone); **AND**
- Patient does not have severe hepatic impairment (e.g., total bilirubin > 3 times the upper limit of normal); **AND**

Prostate Cancer † [1-3]

- Patient has castration-resistant metastatic adenocarcinoma; **AND**
  - Used as a single agent †; **AND**
    - Patient must have been previously treated with docetaxel unless contraindicated or intolerant to docetaxel; **OR**
  - Used in combination with carboplatin ‡; **AND**
    - Used for fit patients with aggressive variant disease (e.g., visceral metastases, low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone

metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (e.g., defects in at least two of the following: PTEN, TP53, and RB1); **AND**

- Patient has received prior docetaxel and no prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, apalutamide, etc.); **OR**
- Patient has received prior novel hormone therapy and no prior docetaxel; **OR**
- Patient has received prior docetaxel and prior novel hormone therapy; **AND**
  - Patient does not have visceral metastases; **OR**

- Patient has castration-resistant metastatic small cell/neuroendocrine prostate cancer; **AND**
  - Used in combination with carboplatin; **AND**
  - Used for fit patients with aggressive variant disease (e.g., visceral metastases, low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (e.g., defects in at least two of the following: PTEN, TP53, and RB1)

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

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 with treatment 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: bone marrow suppression (neutropenia, anemia, thrombocytopenia, and/or pancytopenia), severe hypersensitivity reactions, gastrointestinal adverse reactions (severe diarrhea, nausea, vomiting), urinary disorders including severe hemorrhagic cystitis, renal failure, hepatic impairment, respiratory disorders (interstitial pneumonia/pneumonitis, interstitial lung disease, acute respiratory distress syndrome), etc.

V. Dosage/Administration [1]

Indication	Dose
Prostate Cancer	Administer 20-25 mg/m², 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; February 2021. Accessed February 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cabazitaxel. National Comprehensive Cancer Network, 2022. 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 2022.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 3.2022. National Comprehensive Cancer Network, 2022. 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 2022.
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; TROPIC Investigators. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomized open-label trial. Lancet 2010. Oct 2;376(9747):1147-54. doi: 10.1016/S0140-6736(10)61389-X.
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 Oncology34, no. 15_suppl(May 20, 2016)5006-5006. DOI: 10.1200/JCO.2016.34.15_suppl.5006.
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8. Eisenberger M, Hardy-Bessard AC, Kim CS, et al. Phase III Study Comparing a Reduced Dose of Cabazitaxel (20 mg/m2) and the Currently Approved Dose (25 mg/m2) 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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate

ICD-10	ICD-10 Description
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors

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: https://www.cms.gov/medicare-coverage-database/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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC