Cabazitaxel:
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 in a single-dose vial: 1 vial per 21-day supply
- Cabazitaxel 45 mg/4.5 mL solution for injection in a multiple-dose vial: 1 vial per 21 day supply
- Cabazitaxel 60 mg/6 mL solution for injection in a multiple-dose vial: 1 vial per 21 day supply

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

- Jevtana [J9043]: 60 billable units per 21 days
- Cabazitaxel [J9064]: 50 mg per 21 days

III. Initial Approval Criteria [1,2]

Coverage is provided in the following conditions:

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

Universal Criteria [1-4]

- 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 † ‡ [1-4,1e,4e,6e]

- Patient has castration-resistant metastatic disease; **AND**
    - Used as a single agent †; **AND**

- Patient must have been previously treated with docetaxel unless not a candidate for or intolerant to docetaxel; **OR**

- Used in combination with carboplatin ‡; **AND**
  - Used for fit patients with aggressive variant disease (i.e., visceral metastases, low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (i.e., defects in at least two of the following: PTEN, TP53, and RB1); **AND**
    - Disease has progressed on prior docetaxel and patient has not received prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, apalutamide, etc.); **OR**
    - Disease has progressed on prior novel hormone therapy and patient has not received prior docetaxel; **OR**
    - Disease has progressed on prior docetaxel and prior novel hormone therapy

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

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

IV. Renewal Criteria [1,2]

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 [1,2]

Indication	Dose
Prostate Cancer	**Jevtana** Administer 20-25 mg/m², intravenously, every 3 weeks in combination with an oral corticosteroid **Cabazitaxel** Administer 20 mg/m², intravenously, every 3 weeks in combination with an oral corticosteroid

VI. Billing Code/Availability Information

HCPCS Code(s):

J9043 – Injection, cabazitaxel, 1 mg: 1 billable unit= 1 mg *(Jevtana ONLY)*

- J9064 – Injection, cabazitaxel (sandoz), not therapeutically equivalent to J9043, 1 mg; 1 billable unit = 1 mg
- J9999 – Not otherwise classified, antineoplastic drugs *(Applicable to other unclassified 505(b)(2) NDA for cabazitaxel not otherwise listed)* **§**

NDC(s):

- Jevtana 60 mg/1.5mL solution for injection kit in a single-dose vial: 00024-5824-xx
- Cabazitaxel (Sandoz) 45 mg/4.5 mL solution for injection in a multiple-dose vial: 00781-3186-xx **§**
- Cabazitaxel (Sandoz) 60 mg/6 mL solution for injection in a multiple-dose vial: 00781-3193-xx **§**

§ *Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book:*

Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA

VII. References (STANDARD)

1. Jevtana [package insert]. Bridgewater, NJ; Sanofi-Aventis U.S. LLC; July 2023. Accessed April 2024.
2. Cabazitaxel [package insert]. Princeton, NJ; Sandoz Inc.; January 2023. Accessed April 2024.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cabazitaxel. National Comprehensive Cancer Network, 2024. 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 April 2024.

4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer, Version 3.2024. National Comprehensive Cancer Network, 2024. 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 April 2024.
5. 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.
6. 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.
7. 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.
8. Fizazi K, Kramer G, Eymard JC, et al. Quality of life in patients with metastatic prostate cancer following treatment with cabazitaxel versus abiraterone or enzalutamide (CARD): an analysis of randomized multicentre, open-label, phase 4 study. Lancet Oncol. 2020 Nov;21(11):1513-1525. doi: 10.1016/S1470-2045(20)30449-6.
9. 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.

VIII. References (ENHANCED)

1e. Fizazi K, Scher HI, Molina A, et al. Abiraterone acetate for treatment of metastatic castration-resistant prostate cancer: final overall survival analysis of the COU-AA-301 randomised, double-blind, placebo-controlled phase 3 study. Lancet Oncol. 2012 Oct;13(10):983-92. doi: 10.1016/S1470-2045(12)70379-0. Epub 2012 Sep 18.
2e. Scher H, Fizazi K, Saad F, et al. Increased Survival with Enzalutamide in Prostate Cancer after Chemotherapy. N Engl J Med 2012; 367:1187-1197.
3e. de Wit R, de Bono J, Sternberg CN, et al. Cabazitaxel versus Abiraterone or Enzalutamide in Metastatic Prostate Cancer. N Engl J Med. 2019;381(26):2506–2518. doi:10.1056/NEJMoa1911206.
4e. Corn PG, Heath EI, Zurita A, et al. Cabazitaxel plus carboplatin for the treatment of men with metastatic castration-resistant prostate cancers: a randomised, open-label, phase 1-2 trial

[published correction appears in Lancet Oncol. 2020 Jan;21(1):e14]. Lancet Oncol. 2019;20(10):1432-1443. doi:10.1016/S1470-2045(19)30408-5.

5e. Tannock IF, de Wit R, Berry WR, et al. Docetaxel plus Prednisone or Mitoxantrone plus Prednisone for Advanced Prostate Cancer. N Engl J Med 2004; 351:1502-1512.

6e. Berthold DR, Pond GR, Soban F, de Wit R, Eisenberger M, Tannock IF. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer: updated survival in the TAX 327 study. J Clin Oncol. 2008 Jan 10;26(2):242-5. doi: 10.1200/JCO.2007.12.4008.

7e. Marabelle A, Le DT, Ascierto PA, et al. Efficacy of Pembrolizumab in Patients With Noncolorectal High Microsatellite Instability/Mismatch Repair-Deficient Cancer: Results From the Phase II KEYNOTE-158 Study. J Clin Oncol. 2020 Jan 1;38(1):1-10. doi: 10.1200/JCO.19.02105. Epub 2019 Nov 4.

8e. Aggarwal R, Huang J, Alumkal JJ, et al. Clinical and Genomic Characterization of Treatment-Emergent Small-Cell Neuroendocrine Prostate Cancer: A Multi-institutional Prospective Study. J Clin Oncol. 2018 Aug 20;36(24):2492-2503. doi: 10.1200/JCO.2017.77.6880. Epub 2018 Jul 9. PMID: 29985747; PMCID: PMC6366813.

9e. Loriot Y, Massard C, Gross-Goupil M, et al. Combining carboplatin and etoposide in docetaxel-pretreated patients with castration-resistant prostate cancer: a prospective study evaluating also neuroendocrine features. Ann Oncol. 2009 Apr;20(4):703-8. doi: 10.1093/annonc/mdn694. Epub 2009 Jan 29. PMID: 19179557.

10e. Prime Therapeutics Management. Jevtana Clinical Literature Review Analysis. Last updated April 2024. Accessed April 2024.

Appendix 1 – Covered Diagnosis Codes

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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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