Cabazitaxel:
Cabazitaxel; Jevtana®
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
  - Prior authorization validity may be renewed for up to a maximum of 40 weeks of therapy (20 total doses) for members ≥ 65 years of age receiving 16 mg/m² dose every two weeks.

II. Dosing Limits

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

- Jevtana [J9043]: 120 billable units (120 mg) per 28 days
- Cabazitaxel [J9064]: 120 billable units (120 mg) per 42 days

III. Initial Approval Criteria [1,2]

Prior authorization validity is provided in the following conditions:

- Member 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**
- Member does not have severe hepatic impairment (e.g., total bilirubin > 3 times the upper limit of normal); **AND**

Prostate Cancer † ‡ [1-4,10,1e,4e,6e]

- Member has castration-resistant metastatic disease; **AND**

- Used as a single agent †; **AND**
  - Member 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 members 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 androgen receptor pathway inhibitor (ARPI) therapy and member has not received prior docetaxel; **OR**
    - Disease has progressed on prior docetaxel and prior ARPI 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.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

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

IV. Renewal Criteria [1,2]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet the 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 stabilization of disease or decrease in size of tumor or tumor spread; **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 [1,2,10]

Indication	Dose
Prostate Cancer	**Jevtana** • Administer 20-25 mg/m², intravenously, every 3 weeks in combination with an oral corticosteroid • Alternative dosing option for members ≥ 65 years of age: Administer 16 mg/m², intravenously, every 2 weeks in combination with an oral corticosteroid up to a maximum of 40 weeks of therapy (20 total doses) **Cabazitaxel** • Administer 20 mg/m², intravenously, every 3 weeks in combination with an oral corticosteroid • Alternative dosing option for members ≥ 65 years of age: Administer 16 mg/m², intravenously, every 2 weeks in combination with an oral corticosteroid up to a maximum of 40 weeks of therapy (20 total doses)

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 may be available from several different manufacturers. For a complete list of all available products and NDCs please reference the FDA website at National Drug Code Directory for Cabazitaxel. 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]. Morristown, NJ; Sanofi-Aventis U.S. LLC; May 2025. Accessed February 2026.
2. Cabazitaxel [package insert]. Princeton, NJ; Sandoz Inc.; January 2023. Accessed February 2026.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cabazitaxel. National Comprehensive Cancer Network, 2026. 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 2026.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer, Version 5.2026. National Comprehensive Cancer Network, 2026. 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 2026.
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.

10. Oudard S, Ratta R, Voog E et al. Biweekly vs Triweekly Cabazitaxel in Older Patients With Metastatic Castration-Resistant Prostate Cancer: The CABASTY Phase 3 Randomized Clinical Trial. JAMA Oncol. 2023 Dec 1;9(12):1629-1638. doi: 10.1001/jamaoncol.2023.4255. PMID: 37883073; PMCID: PMC10603579.

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. Aparicio AM, Harzstark AL, Corn PG, et al. Platinum-based chemotherapy for variant castrate-resistant prostate cancer. Clin Cancer Res. 2013 Jul 1;19(13):3621-30. doi: 10.1158/1078-0432.CCR-12-3791. Epub 2013 May 6. PMID: 23649003; PMCID: PMC3699964.

11e. Prime Therapeutics Management. Jevtana Clinical Literature Review Analysis. Last updated February 2026. Accessed February 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
Z85.46	Personal history of 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