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]

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**

Universal Criteria [1-3]

- Must be used in combination with a steroid (e.g. prednisone or dexamethasone); **AND**

Prostate Cancer † [1-3,1e,4e,6e]

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

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)

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 the following: 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, interstitial lung disorders, 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 (STANDARD)

1. Jevtana [package insert]. Bridgewater, NJ; Sanofi-Aventis U.S. LLC; February 2021. Accessed April 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cabazitaxel. National Comprehensive Cancer Network, 2021. 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 by Magellan Rx April 2021.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer, Version 2.2021. National Comprehensive Cancer Network, 2021. 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 by Magellan Rx April 2021.
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.

VIII. References (ENHNACED)

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.

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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. Magellan Health, Magellan Rx Management. Jevtana Clinical Literature Review Analysis. Last updated April 2021. Accessed April 2021.

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): 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

Appendix 3 – CLINICAL LITERATURE REVIEW

OS = overall survival; PFS = progression-free survival; ORR = objective response rate; CR = complete response; PR = partial response; DoR = duration of response; TTP = time to progression; FFS = failure-free survival; EFS = event-free survival; PFR = progression free rate; mCRPC = metastatic castration-resistant prostate cancer; CSPC = castration-sensitive prostate cancer; ADT = androgen-deprivation therapy; SOC = standard of care

Prostate Cancer

Metastatic Castration-Resistant Prostate Cancer – after prior docetaxel/no prior novel hormone therapy							
Regimen	**NCCN Category**	**FDA Approved**	**Trial Design**	**Comparator**	**Primary End-Point**	**Line of Therapy**	**Conclusion**
Cabazitaxel+ prednisone	1 (after docetaxel-based regimen)	Yes (metastatic CRPC previously treated with a docetaxel-containing treatment regimen)	Phase 3 (TROPIC), randomized, open-label, international, multi-center	Mitoxantrone +prednisone	OS	Second-line after docetaxel-containing regimen	• Cabazitaxel improved OS patients with metastatic castration-resistant prostate cancer whose disease has progressed during or after docetaxel-based therapy
Cabazitaxel+ prednisone	1 (after docetaxel-based regimen)	Yes metastatic CRPC previously treated with a docetaxel-containing treatment regimen	Phase 4 (CARD), randomized, multi-center, open-label	Abiraterone or enzalutamide (androgen-signaling-targeted inhibitor)	PFS	Second-line after docetaxel-containing regimen and an androgen-signaling-targeted inhibitor (abiraterone or enzalutamide)	• Cabazitaxel significantly improved a number of clinical outcomes, as compared with the androgen-signaling-targeted inhibitor (abiraterone or enzalutamide), in patients with metastatic castration-resistant prostate cancer who had been previously treated with docetaxel and the alternative androgen-signaling-targeted agent (abiraterone or enzalutamide).
Cabazitaxel + carboplatin	2A certain circumstances	No	Phase 1-2, randomized, open-label	Cabazitaxel	PFS	Second-line	• Carboplatin added to cabazitaxel showed improved PFS compared with cabazitaxel alone for men with

							metastatic castration-resistant prostate cancer.
Abiraterone+ prednisone	1 (after docetaxel-based regimen)	Yes metastatic CRPC or CSPC	Phase 3 (COU-AA-301), randomized, placebo-controlled	Placebo+ prednisone	OS	Second-line after docetaxel-containing regimen	• Abiraterone significantly prolonged OS in patients with metastatic CRPC who have progressed after docetaxel treatment
Enzalutamide	1	Yes	Phase 3 (AFFIRM), double-blind, placebo-controlled	Placebo	OS	Second-line after chemotherapy	• Enzalutamide significantly prolonged the OS of men with mCRPC after chemotherapy
Metastatic Castration-Resistant Prostate Cancer – after prior novel hormone therapy/no prior docetaxel							
Regimen	**NCCN Category**	**FDA Approved**	**Trial Design**	**Comparator**	**Primary End-Point**	**Line of Therapy**	**Conclusion**
Docetaxel	1 preferred	Yes	Phase 3 (TAX 327), randomized Extended follow-up	Mitoxantrone + prednisone (MP)	OS	First-line (chemotherapy naïve)	• Docetaxel every 3 weeks led to superior OS than mitoxantrone
Sipuleucel-T	2A preferred	Yes	Phase 3 (IMPACT), multicenter, randomized, double-blind	Placebo	OS	≤ 2 prior lines of chemotherapy (asymptomatic or minimally symptomatic, no visceral metastases)	• Sipuleucel-T prolonged OS among men with CRPC However, sipuleucel-T had minimal effect on radiographic disease progression and PSA
Cabazitaxel + carboplatin	2A certain circumstances	No	Phase 1-2, randomized, open-label	Cabazitaxel	PFS	Second-line	• Carboplatin added to cabazitaxel showed improved PFS compared with cabazitaxel alone for men with

							metastatic castration-resistant prostate cancer.
Metastatic Castration-Resistant Prostate Cancer – after prior docetaxel and prior novel hormone therapy							
Regimen	**NCCN Category**	**FDA Approved**	**Trial Design**	**Comparator**	**Primary End-Point**	**Line of Therapy**	**Conclusion**
Cabazitaxel	1 preferred	Yes metastatic CRPC previously treated with a docetaxel-containing treatment regimen	Phase 3 (TROPIC), randomized, open-label, international, multi-center	Mitoxantrone +prednisone	OS	Second-line after docetaxel-containing regimen	• Cabazitaxel improved OS patients with metastatic castration-resistant prostate cancer whose disease has progressed during or after docetaxel-based therapy.
Docetaxel rechallenge	2A	No	No clinical literature to support use.				
Pembrolizumab	2A certain circumstances for MSI-H or dMMR	Solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options	Phase 2 (KEYNOTE-158)	N/A	ORR	Subsequent therapy	Pembrolizumab demonstrated a clinical benefit with an overall ORR of 34.3% in patients with previously treated unresectable or metastatic MSI-H/dMMR non-colorectal cancer. This study included 6 patients with cervical cancer.