Cabazitaxel:
Jevtana®; Cabazitaxel§
(Intravenous)

-E-

Document Number: IC-0411

Last Review Date: 03/02/2023
Date of Origin: 01/07/2019
Dates Reviewed: 01/2019, 05/2019, 05/2020, 05/2021, 05/2022, 03/2023

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

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

- Jevtana: 60 billable units per 21 days
- Cabazitaxel: 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 adenocarcinoma; **AND**

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- 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 (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.); **AND**

      – Use of cabazitaxel will be restricted to patients with a contraindication or intolerance to novel hormone therapy; **OR**
    - Patient has received prior novel hormone therapy and no prior docetaxel; **AND**

      – Use of cabazitaxel will be restricted to patients with a contraindication or intolerance to 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); 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,

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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:

- J9043 – Injection, cabazitaxel, 1 mg: 1 billable unit= 1 mg *(Jevtana ONLY)*
- J9999 – Not otherwise classified, antineoplastic drugs *(Cabazitaxel ONLY)*

NDC:

- Jevtana 60 mg/1.5mL solution for injection, single-dose vial: 00024-5824-xx
- Cabazitaxel 45 mg/4.5 mL solution for injection, multiple-dose vial: 00781-3186-xx §
- Cabazitaxel 60 mg/6 mL solution for injection, 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)

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2. Cabazitaxel [package insert]. Princeton, NJ; Sandoz Inc.; January 2023. Accessed January 2023
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cabazitaxel. National Comprehensive Cancer Network, 2023. 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 January 2023.

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4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer, Version 1.2023. National Comprehensive Cancer Network, 2023. 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 January 2023.
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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.

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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: 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

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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

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