# Cabazitaxel (Jevtana®)

**NDC CODE(S)** 00024-5824-XX JEVTANA 60MG/1.5ML Solution (SANOFI PHARMACEUTICALS)
00024-5823-XX JEVTANA 60MG/1.5ML Solution (SANOFI-AVENTIS)

## DESCRIPTION

Cabazitaxel is an antineoplastic agent in the taxane class. It is a semi-synthetic agent prepared with a precursor (10-deacetyl baccatin III) extracted from the needles of certain yew trees. Its antineoplastic activity is as a microtubule inhibitor. Cabazitaxel binds to cellular tubulin which promotes the assembly of microtubules but inhibits microtubular function and breakdown. This halts the cellular mitotic and interphase functions and leads to apoptosis.

## POLICY

- Cabazitaxel for the treatment of prostate cancer is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Cabazitaxel for the treatment of other conditions/diseases is considered ***investigational.***

## MEDICAL APPROPRIATENESS

### INITIAL APPROVAL CRITERIA

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

**Universal Criteria**

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

**Prostate Cancer**

- 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

**Renewal 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 the Initial Approval Criteria; **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, leukopenia, thrombocytopenia, and/or pancytopenia), severe hypersensitivity reactions, gastrointestinal adverse reactions (severe diarrhea, nausea, vomiting), urinary disorders including severe hemorrhagic cystitis, renal failure, or hepatic impairment ~~toxicity~~, interstitial lung disorders, etc.

**DOSAGE/ADMINISTRATION**

| INDICATION | DOSE |
|---|---|
| Prostate Cancer | Administer 20-25 mg/m² , intravenously, every 3 weeks in combination with an oral corticosteroid |

**LENGTH OF AUTHORIZATION**

Coverage will be provided for 6 months and may be renewed.

**DOSING LIMITS**

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

- 60 billable units per 21 days

**APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS**

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

**IMPORTANT REMINDER**

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

**ADDITIONAL INFORMATION**

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

**SOURCES**

1. Jevtana [package insert]. Bridgewater, NJ; Sanofi-Aventis U.S. LLC; February 2021. Accessed March 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 March 2021.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 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 March 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. dDe 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.2010;376:1145-1154. NCT00417079.
6. Sartor AO, Oudard S, Sengelov L, et al. Cabazitaxel vs docetaxel in chemotherapy-naïve (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.
7. 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.
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 Post docetaxel 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.
9. Lexi-Comp Online. (2021, February). AHFS DI. *Cabazitaxel*. Retrieved April 9, 2021 from Lexi-Comp Online with AHFS.
10. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2021, February). *Cabazitaxel*. Retrieved April 9, 2021 from MICROMEDEX Healthcare Series.

**EFFECTIVE DATE** 8/31/2021

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