# MEDICAL POLICY

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| **POLICY TITLE** | **CABAZITAXEL (JEVTANA®)** |
| **POLICY NUMBER** | **MP-2.158** |

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| Original Issue Date (Created): | **9/1/2011** |
| Most Recent Review Date (Revised): | **1/21/2021** |
| **Effective Date:** | **7/1/2021-RETIRED** |



## I. POLICY

Cabazitaxel (Jevtana®) may be considered **medically necessary** for the treatment of prostate cancer when **all** of the following apply:

- Diagnosis of hormone-refractory metastatic prostate cancer
- Given in combination with prednisone
- Previously treated with a docetaxel-containing treatment regimen

**Pediatric Use:** The safety and effectiveness of cabazitaxel (Jevtana®) in pediatric patients have not been established.

The use of cabazitaxel (Jevtana®) for all other indications is considered **investigational,** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this drug for other indications.

**Note:** For patients with late stage metastatic disease (Stage IV), please refer to MP 2.373 Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions for additional guidance.

***Cross-references:***

**MP 2.103** Off-Label Use of Medications
**MP 2.373** Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions
**MP 5.022** Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) with Indium-111 Capromab Pendetide for Prostate Cancer

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## II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

**FEP PPO** - Refer to FEP Medical Policy Manual MP-5.21.27, Jevtana (cabazitaxel). The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

**Medicare Advantage:** "Off-label use of FDA approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen for medically accepted indications may be covered under Medicare if the indications are supported in either one or more Medicare recognized compendia or in peer-reviewed literature. Refer to Medicare Benefit Policy Manual (100-2, Chapter 15, Section 50.4.5- Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen) for the compendia list." *http://www.cms.gov/manuals/Downloads/bp102c15.pdf*

## III. DESCRIPTION/BACKGROUND TOP

First-line therapy for patients with metastatic prostate cancer is medical or surgical castration. Approximately 85% of patients will respond to this therapy, which includes gonadotropin-releasing hormone antagonists or surgery. However, approximately 15% of patients will not respond to hormonal intervention and responders will eventually become refractory to hormonal intervention. For this metastatic hormone-refractory prostate cancer (mHRPC) population, recommended first-line therapy is the combination of docetaxel and prednisone. Cabazitaxel (Jevtana®) has been developed specifically for use in men with mHRPC that fails to respond to a docetaxel-containing regimen.

Cabazitaxel (Jevtana®) is approved by the United States Food and Drug Administration (FDA) for the following indication: in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Cabazitaxel (Jevtana®) is an antineoplastic agent belonging to the taxane class. Cabazitaxel (Jevtana®) is a microtubule inhibitor prepared by semi-synthesis with a precursor extracted from yew needles. Cabazitaxel (Jevtana®) binds to tubulin and promotes its assembly into microtubules while simultaneously inhibiting disassembly. This leads to the stabilization of microtubules, which results in the inhibition of mitotic and interphase cellular functions. Cabazitaxel (Jevtana®) is active in docetaxel-sensitive tumors. In addition, cabazitaxel (Jevtana®) demonstrated activity in tumor models insensitive to chemotherapy including

docetaxel. There are also ongoing clinical trials investigating cabazitaxel (Jevtana®) for the treatment of other types of malignancies.

**BOXED WARNING: Neutropenia and Hypersensitivity**
**Neutropenia:** Neutropenic deaths have been reported. Monitor for neutropenia with frequent blood cell counts. Cabazitaxel (Jevtana®) is contraindicated in patients with neutrophil counts of less than1,500 cells/$mm^3$. Primary prophylaxis with G-CSF is recommended in patients with high-risk clinical features.
**Severe hypersensitivity:** Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the cabazitaxel (Jevtana®) infusion and administration of appropriate therapy. Patients should receive premedication. Cabazitaxel (Jevtana®) is contraindicated in patients who have a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80.

**Dosage and Administration**
Cabazitaxel (Jevtana®) is administered every three weeks as a one-hour intravenous infusion in combination with oral prednisone 10 mg administered daily throughout cabazitaxel (Jevtana®) treatment. The total dose is based on calculation of the Body Surface Area.

**Note:** The dosage and administration information is provided for informational purposes only and should not be used as a source for making prescribing or other medical determinations. Please refer to the manufacturer's full prescribing information for dosage guidelines and other information related to this medication before making any clinical treatment decisions.

## IV. RATIONALE TOP

For information on clinical studies for cabazitaxel (Jevtana®), refer to the Prescribing Information.

## V. DEFINITIONS TOP

**ANTAGONIST** is a substance that stops the action or effect of another substance.

**DOCETAXEL** is a drug used together with other drugs to treat certain types of breast cancer, stomach cancer, prostate cancer, and certain types of head and neck cancer. Docetaxel is a type of mitotic inhibitor. Also called Taxotere.

**GONADOTROPIN-RELEASING HORMONE** is a hormone made by the hypothalamus (part of the brain). GnRH causes the pituitary gland to make and secrete the hormones luteinizing hormone (LH) and follicle stimulating hormone (FSH). These hormones are involved in reproduction.

**METASTASIS** is the manifestation of a malignancy as a secondary growth arising from the primary growth in a new location. The malignant cells may spread through the lymphatic circulation, the bloodstream or avenues such as the cerebrospinal fluid.

**MITOTIC ACTIVITY** refers to the presence of dividing (proliferating) cells. Cancer tissue generally has more mitotic activity than normal tissues.

**TUBULIN** is one of a group of proteins found in high levels in the cell cytoplasm (fluid inside a cell but outside the cell's nucleus). Tubulins are the building blocks of microtubules (narrow, hollow tubes inside a cell), which are involved in cell division and cell movement. Certain anticancer drugs bind to and block the formation of function of tubulins, which may block cell division.

## VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

## VII. DISCLAIMER

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*Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. CODING INFORMATION

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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**Covered when medically necessary:**

| HCPCS Code | Description |
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| J9043 | Injection, Cabazitaxel, 1 mg |

| ICD-10-CM Diagnosis Code | Description |
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| C61 | Malignant neoplasm of prostate |

## IX. REFERENCES

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## X. POLICY HISTORY

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| **MP-2.158** | **CAC 1/25/11** New Policy |
| | **CAC 6/26/12 Consensus review**; no changes, references updated. |

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| | **CAC 9/24/13 Consensus review;** no changes to policy statements references updated. Rationale added. FEP variation revised to refer to the FEP medical policy manual. Administrative code review complete. |
| | **CAC 7/22/14 Consensus**. No change to policy statements. References updated. |
| | **CAC 7/21/15 Consensus review.** No changes to the policy statements. References updated**.** Codes Reviewed. |
| | **CAC 7/26/16 Consensus review.** No changes to policy. Background information and references updated. Codes Reviewed. |
| | **Admin Change 9/1/16** FEP policy change from 5.04.27 to 5.21.27 |
| | **Admin update 1/1/17:** Product variation section reformatted |
| | **CAC 7/25/17 Consensus review.** No changes to the policy. References and rationale reviewed. Coding reviewed. |
| | **2/22/18 Consensus review.** Policy statement unchanged. Description/Background, Rationale and Reference sections updated. |
| | **6/1/18** Policy will be effective for all products. See product variations for any exceptions. Admin correction 8/13/18. |
| | **2/6/19 Consensus review.** Policy statement unchanged. Updated references. |
| | **2/27/20 Consensus review**. Policy statement unchanged. Updated references, coding reviewed. Added note patients with late stage metastatic disease (Stage IV), please refer to MP 2.373 Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions for additional guidance. Effective 4/10/2020. |
| | **1/21/21 Retirement.** This policy will be managed by PRIME. |

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