MEDICAL POLICY

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

Original Issue Date (Created):	**9/1/2011**
Most Recent Review Date (Revised):	**2/6/2019**
Effective Date:	**4/1/2019**

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.

Cross-references:

MP-2.103 Off-Label Use of Medications
MP-2.151 Cellular Immunotherapy for Prostate Cancer
MP-5.022 Radioimmunoscintigraphy Imaging (Monoclonal Antibody Imaging) with Indium-111 Capromab Pendetide for Prostate Cancer

II. PRODUCT VARIATIONS

TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

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

FEP PPO - Refer to FEP Medical Policy Manual MP-5.21.27, Jevtana (cabazitaxel). The FEP Medical Policy Manual can be found at: www.fepblue.org.

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 $\leq$1,500 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 luteinizing hormone (LH) and follicle stimulating hormone (FSH). These hormones are involved in reproduction. Also called GnRH.

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.

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

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 contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

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. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES

TOP

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IX. CODING INFORMATION

TOP

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.

Covered when medically necessary:

HCPCS Code	Description
J9043	Injection, Cabazitaxel, 1 mg

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

X. POLICY HISTORY

TOP

MP-2.158	**CAC 1/25/11** New Policy
	CAC 6/26/12 Consensus review; no changes, references updated.
	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 7/26/2016 Consensus review. No changes to policy. Background information and references updated. Codes Reviewed.
	Admin Change 9/1/2016 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.

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POLICY NUMBER	MP-2.158

	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.

Top