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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Antineoplastic Agents	**Original Policy Date:**	November 8, 2012
Subject:	Jevtana	**Page:**	1 of 4

Last Review Date: June 16, 2022

Jevtana

Description

Jevtana (cabazitaxel)

Background
Jevtana is in the taxane class and acts by binding to tubulin and promoting its assembly into microtubules while inhibiting disassembly. This causes the stabilization of microtubules which in turn inhibits mitotic and interphase cellular functions. The drug is administered as a one hour intravenous infusion every three weeks in combination with 10 mg oral prednisone taken daily throughout the Jevtana treatment. Other potential strategies for treatment in the setting of post-docetaxel progression of prostate cancer include ixabepilone, mitoxantrone/prednisone, platinum agents, immunotherapies, and molecularly targeted agents (1-2).

Regulatory Status
FDA-approved indication: Jevtana is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen (1).

Jevtana carries a boxed warning for severe neutropenia Obtain frequent blood counts to monitor for neutropenia. Do not give Jevtana if neutrophil counts are ≤1,500 cells/mm3. Severe hypersensitivity can occur and may include generalized rash/erythema, hypotension and bronchospasm. To reduce the risk and/or severity of hypersensitivity of the infusion, the patient must be premedicated at least 30 minutes prior to each dose of Jevtana with an antihistamine, corticosteroid, and a H2 antagonist. Antiemetic prophylaxis is recommended and can be given

if needed. Jevtana is contraindicated if there is a history of severe hypersensitivity reactions to polysorbate 80. Jevtana should not be given to patients with hepatic impairment (1).

The safety and effectiveness of Jevtana have not been established in pediatric patients (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Jevtana may be considered **medically necessary** in patients 18 years of age or more with hormone refractory metastatic prostate cancer and if the conditions indicated below are met.

Jevtana may be considered **investigational** in patients who are less than18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Hormone refractory metastatic prostate cancer

AND ALL of the following:

a. Previously treated with a docetaxel containing treatment regimen
b. Used in combination with prednisone
c. Neutrophil count >1500 cells/µL and agreement to monitor during therapy
d. **NO** hepatic impairment
    i. Bilirubin is not greater than or equal to upper limit of normal (ULN)
    ii. AST and/ or ALT is not greater than or equal to 1.5 times the ULN

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Hormone refractory metastatic prostate cancer

AND ALL of the following:

a. Using in combination with prednisone
b. Neutrophil count >1500 cells/µL and agreement to continue to monitor during therapy
c. Has **NOT** developed hepatic impairment
   i. Bilirubin is not above ULN
   ii. ALT and/or AST are less than 1.5 times ULN

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Jevtana is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. There are several potential patient safety concerns with treatment. Jevtana can cause serious side effects such as dangerously low neutrophil counts, severe allergic reactions and kidney failure. Frequent and routine blood tests need to be monitored during treatment (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Jevtana while maintaining optimal therapeutic outcomes.

References

1. Jevtana [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; February 2021.
2. NCCN Drugs & Biologics Compendium® Cabazitaxel 2022. National Comprehensive Cancer Network, Inc. Accessed on April 19, 2022.

Policy History

Date	Action
October 2012	New policy
December 2012	Annual review and update
March 2014	Annual editorial review and reference update. Addition of no hepatic impairment added to initiation of therapy
September 2015	Annual editorial review and reference update
June 2016	Annual editorial review and reference update Policy code changed from 5.04.27 to 5.21.27
June 2017	Annual editorial review and reference update Addition of age limit to renewal criteria
June 2018	Annual editorial review and reference update
June 2019	Annual review and reference update
June 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.