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5.21.027

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	November 8, 2012
Subject:	Jevtana	**Page:**	1 of 4

Last Review Date: June 13, 2024

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 metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen (1).

Jevtana carries a boxed warning for severe hypersensitivity and neutropenia. Obtain frequent blood counts to monitor for neutropenia. Do not give Jevtana if neutrophil counts are ≤1,500 cells/mm^3. Severe hypersensitivity reactions 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 H_2 antagonist. Antiemetic prophylaxis is recommended and can be given if needed. Jevtana is contraindicated if there is a

history of severe hypersensitivity reactions to cabazitaxel or polysorbate 80. Jevtana should not be given to patients with severe hepatic impairment (total bilirubin > 3 x Upper Limit of Normal (ULN) (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** if the conditions indicated below are met.

Jevtana may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Metastatic castration-resistant 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/mm^3 and agreement to monitor during therapy
d. **NO** severe hepatic impairment (total bilirubin >3 x ULN)

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Metastatic castration-resistant prostate cancer

AND ALL of the following:

a. Using in combination with prednisone
b. Neutrophil count >1500 cells/mm^3 and agreement to continue to monitor during therapy
c. **NO** severe hepatic impairment (total bilirubin >3 x 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 metastatic castration-resistant 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; July 2023.

2. NCCN Drugs & Biologics Compendium® Cabazitaxel 2024. National Comprehensive Cancer Network, Inc. Accessed on May 14, 2024.

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
June 2023	Annual review and reference update. Changed policy number to 5.21.027
May 2024	Per PI, changed indication from hormone refractory to metastatic castration-resistant prostate cancer. Changed requirement to “no severe hepatic impairment (total bilirubin > 3 x ULN)”
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.