

POLICY: Oncology – Jevtana® (cabazitaxel injection for intravenous use – Sanofi-Aventis LLC)

EFFECTIVE DATE: 1/1/2021

LAST REVISION DATE: 03/08/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Jevtana, a microtubule inhibitor, is indicated in combination with prednisone for the treatment of patients with **metastatic castration-resistant prostate cancer (CRPC)** previously treated with a docetaxel-containing treatment regimen.¹

Guidelines

The National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 1.2023 – September 16, 2022) list Jevtana, in combination with a steroid, as a “Preferred” regimen for patients who have received prior docetaxel and novel hormone therapy without visceral metastases (category 1), or with visceral metastases (category 2B).^{2,3} Jevtana in combination with a steroid is a “Preferred” regimen for patients who have received prior docetaxel without prior novel hormone therapy (category 2A). The guidelines note that Jevtana (in combination with steroid) can also be considered in patients who are not candidates for docetaxel or are intolerant to docetaxel (category 2A). Jevtana in combination with carboplatin is “Useful in Certain Circumstances” in patients who have received prior docetaxel and/or novel hormone therapy. In addition, Jevtana in combination with carboplatin and a steroid (category 2A) is recommended for the treatment of small cell/neuroendocrine prostate cancer in fit patients with aggressive variant prostate cancer or in patients with unfavorable genomics defined as having defects in at least two of the following: phosphatase and tensin homolog (*PTEN*), tumor protein p53 (*TP53*), and retinoblastoma transcriptional corepressor 1 (*RBI*).

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Jevtana. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the criteria and dosing for the indication. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Jevtana as well as the monitoring required for adverse events and long-term efficacy, approval requires Jevtana to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Jevtana is recommended in those who meet the following criteria:

FDA-Approved Indication

-
- 1. Prostate Cancer.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
- A)** Patient has metastatic castration-resistant prostate cancer; AND
 - B)** The medication will be used in combination with a systemic corticosteroid (e.g., prednisone); AND
 - C)** Patient meets one of the following criteria (i, ii, iii, or iv):
 - i.** Patient has small cell/neuroendocrine prostate cancer and meets one of the following criteria (a or b):
 - 1. According to the prescriber, the patient is fit and has aggressive variant disease; OR
 - 2. Patient has unfavorable genomics with defects in at least two of the following: phosphatase and tensin homolog (*PTEN*), tumor protein p53 (*TP53*), and retinoblastoma transcriptional corepressor 1 (*RBI*); OR
 - ii.** Patient has been previously treated with a docetaxel-containing treatment regimen; OR
 - iii.** Patient is not a candidate or is intolerant to docetaxel therapy, according to the prescriber; OR
 - iv.** Patient has been treated with novel hormone therapy; AND
Note: Examples of novel hormone therapy include abiraterone, Erleada (apalutamide tablet), Nubeqa (darolutamide tablet), and Xtandi (enzalutamide tablet and capsule).
 - D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 25 mg/m² administered intravenously once every three weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Jevtana is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Jevtana[®] intravenous infusion [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; February 2021.
2. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 28, 2023. Search term: cabazitaxel.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 28, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Prostate Cancer: Added small cell/neuroendocrine prostate cancer and unfavorable genomics with defects in at least two of the following as additional options for approval.	03/02/2022
Annual Revision	Prostate Cancer: Moved “patient has unfavorable genomics” to an option for approval for small cell/neuroendocrine prostate cancer. Added “patient is fit with aggressive variant disease” as another option for approval for small cell/neuroendocrine prostate cancer. Added “patient has been treated with novel hormone therapy” as an option for approval.	03/08/2023