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

APPROVAL DATE: 02/20/2019

OVERVIEW

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

Guidelines

The National Comprehensive Cancer Network (NCCN) prostate cancer guidelines (version 4.2018) lists Jevtana as one of the category 1 recommended therapies in the post-docetaxel setting for metastatic CRPC.[2,3] The guidelines note that Jevtana (in combination with steroid) can be considered in patients who are not candidates for docetaxel or are intolerant to docetaxel; however, current data do not support greater efficacy of Jevtana over docetaxel.[2]

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(s). 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, initial 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 one of the following criteria:

FDA-Approved Indications

1. **Prostate Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** The patient has metastatic castration-resistant prostate cancer; AND
   - **B)** Jevtana will be used in combination with a systemic corticosteroid (e.g., prednisone); AND
   - **C)** The patient meets one of the following criteria (i or ii):
     - **i.** The patient has been previously treated with a docetaxel-containing treatment regimen; OR
     - **ii.** The patient is not a candidate or is intolerant to docetaxel therapy, according to the prescribing physician; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 25 mg/m^2 administered once every three weeks..

CONDITIONS NOT RECOMMENDED FOR APPROVAL

1. **Other Indications.** Coverage is not recommended for circumstances not listed in the Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). Criteria will be updated as new published data are available.

REFERENCES

1. Jevtana® Intravenous Infusion [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; January 2018.
2. The NCCN Drugs and Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on November 19, 2018. Search term: cabazitaxel.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 4.2018 – August 15, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on February 11, 2019.

HISTORY

Type of Revision	Summary of Changes*	Approval Date
New policy	--	11/21/2018
Early annual revision	Added criteria to allow if patient cannot tolerate or is not a candidate for docetaxel therapy, as per guidelines. Changed dosing to allow for "up to" 25 mg/m^2.	02/20/2019