

Jevtana (cabazitaxel)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Jevtana (cabazitaxel) 60 mg/1.5mL intravenous solution for injection

APPROVAL CRITERIA

Requests for Jevtana (cabazitaxel) may be approved if the following criteria are met:

- I. Individual has a diagnosis of metastatic castration-resistant prostate cancer (Label, NCCN 1); **AND**
- II. Individual is using in combination with prednisone; **AND**
- III. Disease has progressed during or after treatment with a docetaxel-containing regimen (or in patients who are not candidates for, or are intolerant of docetaxel) (Label, NCCN 2A); **AND**
- IV. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status is 0-2;

OR

- V. Individual has a diagnosis of metastatic castration-resistant prostate cancer (NCCN 2A); **AND**
- VI. Individual is using in combination with carboplatin and concurrent steroid treatment; **AND**
- VII. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0; **AND**
- VIII. Individual is using for one of the following disease types:
 - A. Small cell/neuroendocrine prostate cancer; **OR**
 - B. Distant metastatic prostate cancer disease; **OR**
 - C. Unfavorable genomics (defects in at least two of the following, PTEN, TP53, and RB1).

Requests for Jevtana (cabazitaxel) may not be approved for the following:

- I. For the treatment of all other solid tumors and uses, including but not limited to appendiceal cancer, bladder cancer, brain tumor, breast cancer, head and neck cancer, lung cancer, melanoma and pancreatic cancer; **OR**
- II. Individual has severe hepatic impairment (total bilirubin >3 X ULN); **OR**
- III. Individual has neutrophil counts of $\leq 1,500/\text{mm}^3$; **OR**
- IV. When the above criteria are not met, and for all other indications.

Note:

Jevtana has a black box warning for neutropenia and hypersensitivity. Jevtana is contraindicated in patients with neutrophil counts of $\leq 1,500$ cells/mm³. Jevtana is also contraindicated in patients who have a history of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80. Jevtana is also contraindicated in patients with severe hepatic impairment (total bilirubin >3 x ULN).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 14, 2023.
6. Prostate Cancer. V1.2023. Revised September 16, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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