Clinical Criteria

Subject:	Jevtana (cabazitaxel)		
Document #:	ING-CC-0114	**Publish Date:**	~~06/21/2021~~06/20/2022
Status:	Revised	**Last Review Date:**	~~05/21/2021~~05/20/2022

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Overview

This document addresses the use of Jevtana (cabazitaxel). Jevtana is a microtubule inhibitor, which binds to tubulin and promotes its assembly into microtubules. At the same time, cabazitaxel inhibits disassembly of microtubules by stabilizing tubulin.

The FDA approved indications for Jevtana includes use in metastatic castration-resistant prostate cancer in combination with prednisone previously treated with a docetaxel-containing treatment regimen.

Jevtana has a black box warning for neutropenia and hypersensitivity. Jevtana is contraindicated in patients with neutrophil counts of ≤1,500 cells/mm^3. 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).

Other Uses

Cabazitaxel has also been evaluated as a treatment for other indications, including advanced gastric cancer, brain tumors, breast cancer, small cell lung cancer, and other solid malignancies (appendiceal, melanoma, lung, pancreas, bladder, and head and neck cancer). In a randomized phase II/III study of comparing cabazitaxel to vinflunine in individuals with metastatic or locally advanced transitional cell carcinoma of the urothelium, cabazitaxel showed a lack of efficacy as second-line therapy in the treatment of bladder cancer. The current peer-reviewed published literature does not support that the use of cabazitaxel to treat these conditions provides additional benefit compared to other chemotherapy regimens. The FDA has not approved use of cabazitaxel in the treatment of any of these conditions.

Jevtana has a black box warning for neutropenia. Neutropenic deaths have been reported. Monitor for neutropenia with frequent blood cell counts. Jevtana is contraindicated in those with neutrophil counts of ≤ 1,500 cells/mm^3. Jevtana is also contraindicated in those with a history of severe hypersensitivity reactions to cabazitaxel or to other drug formulated with polysorbate 80, severe hepatic impairment (total bilirubin >3 X ULN), and in pregnancy.

Definitions and Measures

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Jevtana (cabazitaxel)

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 of 0-2.

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 ≤1,500/mm^3; **OR**
~~III.~~ IV. When the above criteria are not met, and for all other indications.

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Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9043	Injection, cabazitaxel, 1 mg [Jevtana]

ICD-10 Diagnosis

C61	Malignant neoplasm of prostate
Z19.2	Hormone resistant malignancy status
Z85.46	Personal history of malignant neoplasm of prostate

Document History

Revised: 05/20/2022
Document History:

- 05/20/2022 – Annual Review: Update may not be approved criteria. Coding Reviewed: No changes.
- 05/21/2021– Annual Review: Update Jevtana criteria to include contraindications added to the FDA label. Coding Reviewed: No changes.
- 05/15/2020– Annual Review: Update Jevtana criteria to standardize prostate cancer diagnosis language. Coding review: No changes
- 08/16/2019– Annual Review: Update criteria for clarification on use when an individual may be intolerant to or not a candidate for docetaxel. Update may not be approved criteria with contraindications and exclusion criteria from clinical trials. Coding Reviewed: No changes.
- 05/17/2019 – Annual Review: Initial review of Jevtana (cabazitaxel). Minor wording and formatting changes. Coding Reviewed: No changes.

References

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5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 23, 2022.
    a. Prostate Cancer. V3.2022. Revised January 10, 2022.

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