Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Cabazitaxel (Jevtana®)	MP-RX-FP-47-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of cabazitaxel (Jevtana®), a microtubule inhibitor approved by the Food and Drug Administration (FDA) in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

Background Information

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 is recommended with a 2A recommendation from NCCN Drugs and Biologics Compendia and the NCCN CPG as useful in certain circumstances in combination with concurrent steroid ± carboplatin for castration-resistant distant metastatic (M1) disease (for fit patients with aggressive variant prostate cancer (visceral metastases, low prostate-specific antigen and bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genomics (defects in ≥2 of the following: PTEN, TP53, and RB1)).

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).

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

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- 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.

Approved Indications

Cabazitaxel (Jevtana®), in combination with prednisone, is indicated by the FDA for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

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.

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9043	Injection, cabazitaxel, 1 mg [Jevtana]
J9064	Inj, cabazitaxel (Sandoz)

ICD-10	Description
C61	Malignant neoplasm of prostate
Z19.2	Hormone resistant malignancy status
Z85.46	Personal history of malignant neoplasm of prostate

Medical Necessity Guidelines

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.

Cabazitaxel (Jevtana®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of metastatic castration-resistant prostate cancer (Label, NCCN 1); **AND**
   - A. Individual is using in combination with prednisone; **AND**
   - B. 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**
   - C. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2;

OR

ii. Individual has a diagnosis of metastatic castration-resistant prostate cancer (NCCN 2A); **AND**
   - A. Individual is using in combination with carboplatin and concurrent steroid treatment; **AND**

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B. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
C. Individual is using for one of the following disease types:
    1. Small cell/neuroendocrine prostate cancer; **OR**
    2. Distant metastatic prostate cancer disease; **OR**
    3. Unfavorable genomics (defects in at least two of the following, PTEN, TP53, and RB1).

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Cabazitaxel (Jevtana®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of an unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
    A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
    B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Jevtana (cabazitaxel) may not be approved for the following:
    a. 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.
    b. Individual has severe hepatic impairment (total bilirubin >3 X ULN).
    c. Individual has neutrophil counts of ≤1,500/mm^3.
    d. When the above criteria (Section A- Criteria for Initial Approve) are not met, and for all other indications.

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Cabazitaxel (Jevtana®)	Usual dose: 20 mg/m^2 i.v. every three weeks in combination with oral prednisone 10 mg administered daily throughout Jevtana treatment. Max. dose: A dose of 25 mg/m^2 can be used in select patients at the discretion of the treating healthcare provider.
Exceptions	

• Dosing calculation based on Body Surface Area (BSA)
• Dose should be modified in patients with hepatic impairment:
  ○ Mild hepatic impairment (total bilirubin >1 to ≤1.5 × Upper Limit of Normal (ULN) or AST >1.5 × ULN): Maximum Jevtana dose is 20 mg/m^2.
  ○ Moderate hepatic impairment (total bilirubin >1.5 to ≤3 × ULN and AST = any): Maximum Jevtana dose is 15 mg/m^2 based on tolerability data in these patients; however, the efficacy of this dose is unknown.
  ○ Severe hepatic impairment (total bilirubin >3 × ULN): Jevtana is contraindicated.
• Coadministration of strong CYP3A4 Inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole) with Jevtana should be avoided. If patients require coadministration of a strong CYP3A inhibitor, consider reducing Jevtana dose by 25%.	

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Reference Information

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.
    a. Prostate Cancer. V1.2023. Revised September 16, 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.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Select Review	Wording and formatting and ECOG correction.	N/A	N/A
Select Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	3/25/2024	5/9/2024
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 10/22/2024