CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL ONCOLOGY

Cabazitaxel (Jevtana®)

Version: 1.1

EFFECTIVE DATE: 1/1/2024

NantHealth® | Eviti®

Please note the following:

Cabazitaxel (Jevtana®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Cabazitaxel (Jevtana): Discussion

Cabazitaxel is a novel second-generation, semisynthetic microtubule inhibitor (specifically, a taxane derivative) that works by disrupting the microtubular network that is essential for mitotic and interphase cellular functions and causes inhibition of cell division and cell death.[1]

Cabazitaxel is primarily metabolized through CYP3A. Strong CYP3A inhibitors (e.g. ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole) may increase plasma concentrations of cabazitaxel. Avoid the coadministration of cabazitaxel with strong CYP3A inhibitors. If patients require coadministration of a strong CYP3A inhibitor, consider a 25% cabazitaxel dose reduction.

Cabazitaxel is associated with several adverse reactions including bone marrow suppression, hypersensitivity reactions, gastrointestinal adverse reactions, renal failure, urinary disorders including cystitis, respiratory disorders, and hepatic laboratory abnormalities.[2]

Cabazitaxel should be given with concurrent steroids (daily prednisone or dexamethasone on the day of chemotherapy). Physicians should follow current guidelines for prophylactic white blood cell growth factor use, particularly in this heavily pretreated, high-risk population. In addition, supportive care should include antiemetics (prophylactic antihistamines, H2 antagonists, and corticosteroids prophylaxis), and symptom-directed antidiarrheal agents.[3]

Note:
1. Neutropenic deaths have been reported. Obtain frequent blood counts to monitor for neutropenia.
2. Severe hypersensitivity can occur and may include generalized rash/erythema, hypotension, and bronchospasm.
3. Contraindicated if history of severe hypersensitivity reactions to cabazitaxel or to drugs formulated with polysorbate 80. [2]

Cabazitaxel is 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.[2]

The National Comprehensive Cancer Network (NCCN) endorses cabazitaxel in the following cancer types: prostate cancer.[3]

Cabazitaxel: Definitions

- **Castration-Resistant Prostrate Cancer (CRPC) -** A stage in prostate cancer progression where the disease continues to advance despite treatments intended to reduce testosterone levels. This indicates that cancer cells have developed mechanisms to sustain growth and survival independent of testosterone suppression.
- **Food and Drug Administration (FDA) -** The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **National Comprehensive Cancer Network (NCCN) -** An alliance of more than 30 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.

Cabazitaxel: Policy

Coverage of cabazitaxel will be provided for FDA-approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

Cabazitaxel will be considered for coverage when the following criteria are met:

Prostate Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. In combination with carboplatin with concurrent steroid for treatment of M1 castration-resistant small cell/neuroendocrine prostate cancer (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 genetic mutations in at least two of the following: PTEN, TP53, and RB1; OR
4. As a single agent given with concurrent steroid for castration-resistant distant metastatic (M1) disease and if received and if the patient has received one of the following:
   a) Prior docetaxel and no prior novel hormone therapy
   b) Prior docetaxel and prior novel hormone therapy
   c) In patients who are either not candidates for or are intolerant of docetaxel; OR

5. In combination with carboplatin with concurrent steroid for castration-resistant distant metastatic (M1) disease for fit patients with aggressive variant prostate cancer (visceral metastases, low prostate-specific antigen, bulky disease, high LDH, high CEA, lytic bone metastases, neuroendocrine prostate cancer histology) or unfavorable genetic mutations in at least two of the following PTEN, TP53, and RB1 and if the patient received prior:
   a) Prior docetaxel and no prior novel hormone therapy
   b) Prior novel hormone therapy and no prior docetaxel
   c) Prior docetaxel and prior novel hormone therapy.[2,3]

Note:
Continue androgen deprivation therapy (ADT) to maintain castrate levels of serum testosterone (<50 ng/dL)

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Cabazitaxel: References

1. WCG Center Watch. https://www.centerwatch.com/directories/1067-fda-approved-drugs/listing/3680-jevtana-cabazitaxel. Accessed July 18, 2024.
2. Cabazitaxel (Jevtana®): Package Insert. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208715s000lbl.pdf. Accessed July 18, 2024.
3. National Comprehensive Cancer Network Guidelines. Prostate Cancer). https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 18, 2024.

Cabazitaxel: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C61	Malignant neoplasm of the prostate
J9043	Cabazitaxel (Jevtana®)

Cabazitaxel: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	6/1/2023, 7/18/2024
3	Policy Revision Dates:	7/18/2024
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	8/7/2023, 8/15/2024
6	Revision Changes:	7/18/2024 - Discussion section updated, added definition for castration resistant prostate cancer, added additional adverse reactions