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Retired
Effective Date: 02/02/2023

# **Jevtana**® (cabazitaxel)

**HCPCS:** J9043

**Policy:**

*Requests must be supported by submission of chart notes and patient specific documentation.*

A. Criteria:
   a. FDA approved indication
   b. FDA approved age
   c. Prescribed by or in consultation with an oncologist
   d. Must have had prior treatment with a docetaxel-containing treatment regimen
   e. Must be given in combination with prednisone
   f. Neutrophil count > 1,500 cells/$mm^3$
   g. ECOG performance status of 0 - 2

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for up to 6 months at a time
   c. Renewal Criteria: Treatment continued until unacceptable toxicity or disease progression

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

**Background Information:**

- Jevtana is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen. Per the 2022 National Comprehesive Cancer Network (NCCN) treatment guidelines for prostate cancer Jevtana should be continued until unacceptable toxicity or disease progression.

- The efficacy and safety were evaluated in the TROPIC trial, a randomized, open-label, international, multi-center study of 755 patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen. This study included patients over 18 years of age with an ECOG performance status score of 0 – 2. Patients had to have neutrophils greater than 1,500 cells/$mm^3$. Patients were randomized to receive either Jevtana 25 mg/$m^2$ every 3 weeks with prednisone or to mitoxantrone 12 mg/$m^2$ every 3 weeks with prednisone. The endpoints of tumor response and overall survival were statistically significant in the Jevtana arm compared to the mitoxantrone arm.

- In the PROSELICA trial, a noninferiority, multicenter, randomized, open-label study of 1200 patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing regimen, subjects were randomized to receive either Jevtana 25 mg/$m^2$ or 20 mg/$m^2$ dose. Overall survival was the major efficacy outcome. The study demonstrated noninferiority in overall survival between the two treatment arms. The estimated median overall survival was 15.1 months on Jevtana 20 mg/$m^2$ and 15.9 months on the 25 mg/$m^2$ dose. The observed hazard ratio of overall survival was 1.042 (97.78% CI: 0.886, 1.224).

**References:**


1. Jevtana [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; February 2021.
2. National Comprehensive Cancer Network. Prostate Cancer (Version 4.2022). 2022 May 10. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed on August 22, 2022.
3. Keizman D, Maimon N, Gottfried M. Metastatic hormone refractory prostate cancer: recent advances in standard treatment paradigm, and future directions. Am J Clin Oncol. 2014 Jun; 37 (3): 289 – 96.
4. Oudard S. TROPIC: phase III trial of cabazitaxel for the treatment of metastatic castration-resistant prostate cancer. Future Oncol. 2011 Apr; 7 (4): 497 - 506.
5. Eisenberger M, Hardy-Bessard AC, Kim CS, et al. Phase III study comparing a reduced dose of cabazitaxel (20 mg/$m^2$) and the currently approved dose (25 mg/$m^2$) in post-docetaxel patients with metastatic castration-resistant prostate cancer-PROSELICA. J Clin Oncol. 2017 Oct 1; 35 (28): 3198 - 206.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.0</td><td>Effective Date: 02/02/2023</td><td>Retiring policy as drug will no longer be part of the prior authorization program</td></tr>
<tr><td>1.9</td><td>Effective Date: 10/06/2022</td><td>Updated approval length to allow for FDA recommended dosing or up to 6 months at a time</td></tr>
<tr><td>1.8</td><td>Effective Date: 10/07/2021</td><td>Annual review of policy. No changes were made to the criteria.</td></tr>
<tr><td>1.7</td><td>Effective Date: 02/01/2020</td><td>UM medical management system update for BCBS<br><table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.6</td><td>Effective Date: 10/08/2020</td><td>Annual Review</td></tr>
<tr><td>1.5</td><td>Effective Date: 01/01/2020</td><td>UM medical management system update for BCNA and MAPPO<br><table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.4</td><td>Effective Date: 11/07/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.3</td><td>Effective Date: 11/01/2018</td><td>Updated criteria per oncology vendor</td></tr>
<tr><td>1.2</td><td>Effective Date: 08/09/2018</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/10/2017</td><td>New Criteria Document created</td></tr>
<tr><td>1.0</td><td>Effective Date: 07/01/2015</td><td>UM medical management system update for BCN<br><table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm).*