BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Cabazitaxel (Jevtana®)

File Name:	cabazitaxel_jevtana
Origination:	8/2016
Last CAP Review:	4/2020
Next CAP Review:	4/2021
Last Review:	4/2020

Description of Procedure or Service

Cabazitaxel (Jevtana) is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Cabazitaxel (Jevtana) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Cabazitaxel (Jevtana) is covered

Cabazitaxel (Jevtana) is considered medically necessary in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Use of Cabazitaxel (Jevtana) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

When Cabazitaxel (Jevtana) is not covered

Cabazitaxel (Jevtana) is considered not medically necessary and therefore not covered when above criteria are not met.

Cabazitaxel (Jevtana®)

Cabazitaxel (Jevtana) is considered investigational when used for:

1. Non-cancer indications; **OR**

2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under "When Cabazitaxel (Jevtana) is covered."

Policy Guidelines

Recommended dose is 20 mg/m^2 administered every three weeks as a one-hour intravenous infusion in combination with oral prednisone 10 mg administered daily throughout Jevtana treatment. A dose of 25 mg/m^2 can be used in select patients at the discretion of the treating healthcare provider.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J9043, S0353, S0354

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/201023lbl.pdf

Medical Director review 8/2016

Medical Director review 3/2017

Specialty Matched Consultant Advisory Panel 4/2017

Specialty Matched Consultant Advisory Panel 4/2018

Sanofi-aventis U.S. LLC. Jevtana (cabazitaxel) injection for intravenous use. Prescribing Information. Bridgewater, NJ:Sanofi-aventis; Revised 1/2018. Available at: http://products.sanofi.us/jevtana/jevtana.html. Accessed May 2018.

Medical Director review 6/2018

Specialty Matched Consultant Advisory Panel 4/2019

Specialty Matched Consultant Advisory Panel 4/2020

Policy Implementation/Update Information

12/30/16 New policy developed. Cabazitaxel (Jevtana) is considered medically necessary in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. Reference added. Medical Director review 8/2016. Added HCPCS codes S0353, S0354 to Billing/Coding section. Notification given 12/30/16 for effective date 4/1/17. (lpr)

5/26/17 Added the following statement to "When Covered" section: "Use of Cabazitaxel (Jevtana) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either: In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); OR In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached". Under "When Not Covered" section, added the statement "Cabazitaxel (Jevtana) is considered investigational when used for: 1)Non-cancer indications; **OR** 2) When criteria are not met regarding FDA labeling **OR** strong endorsement/ support by nationally recognized compendia, as stated under "When Cabazitaxel (Jevtana) is covered." Added the following statements under "Policy Guidelines" section: 1)Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy, Investigational (Experimental) Services." 2) Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia. Medical director review 3/2017. Specialty Matched Consultant Advisory Panel review 4/26/2017. No change to policy statement. (lpr)

6/29/18 Updated recommended dose within "Policy Guidelines" section. References added. Specialty Matched Consultant Advisory Panel review 4/25/2018. No change to policy statement. Medical Director review 6/2018. (krc)

4/30/19 Specialty Matched Consultant Advisory Panel review 4/17/2019. No change to policy statement. (krc)

6/9/20 Specialty Matched Consultant Advisory Panel review 4/15/2020. No change to policy statements. (krc)