

Clinical Policy: Cabazitaxel (Jevtana)

Reference Number: PA.CP.PHAR.316

Effective Date: 01/18

Last Review Date: 04/19

[Coding Implications](#)

[Revision Log](#)

Description

Cabazitaxel (Jevtana[®]) is a microtubule inhibitor.

FDA Approved Indication(s)

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

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness[®] that Jevtana is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of prostate cancer;
2. Disease is hormone-refractory* and metastatic;
3. Prescribed by or in consultation with an oncologist or urologist;
4. Previously treated with a docetaxel-containing treatment regimen;
5. At the time of request, member has none of the following contraindications:
 - a. Neutrophil counts of $\leq 1,500/\text{mm}^3$;
 - b. Severe hepatic impairment (total bilirubin $> 3 \times$ upper limit of normal);
6. Dose does not exceed $25 \text{ mg}/\text{m}^2$ once every 3 weeks.

**Hormone-refractory prostate cancer indicates that disease has progressed despite androgen deprivation therapy (e.g., luteinizing hormone-releasing hormone [LHRH] agonists [e.g., leuprolide, goserelin], first-generation antiandrogens [e.g., nilutamide, flutamide], second-generation antiandrogens [e.g., enzalutamide], LHRH antagonists [e.g., degarelix]).*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53

II. Continued Approval

A. Prostate Cancer (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or the Continuity of Care policy (PA.LTSS.PHAR.01) applies, or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed $25 \text{ mg}/\text{m}^2$ once every 3 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
docetaxel	Androgen-deprivation therapy with docetaxel 75 mg/m ² for 6 cycles	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Boxed warning: neutropenia and hypersensitivity
- Contraindications:
 - Neutrophil counts of $\leq 1,500/\text{mm}^3$
 - History of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80
 - Severe hepatic impairment (total bilirubin $> 3\times$ upper limit of normal)
 - pregnancy

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9043	Injection, cabazitaxel, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: added COC; removed “prescribed in combination with prednisone” per NCCN prostate cancer guidelines ver 3.2018; references reviewed and updated.	07/18	
2Q 2019 annual review: added prescriber requirement; references reviewed and updated.	04/19	

References

1. Jevtana Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US LLC; January 2018. Available at: <https://www.jevtanapro.com/>. Accessed February 26, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed February 26, 2019.
3. Cabazitaxel. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 26, 2019.
4. National Comprehensive Cancer Network. Prostate Cancer Version 01.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 26, 2019.