Clinical Policy: Cabazitaxel (Jevtana)

Reference Number: PA.CP.PHAR.316
Effective Date: 01/2018
Last Review Date: 04/2026

Description
Cabazitaxel (Jevtana®) is a microtubule inhibitor.

FDA Approved Indication(s)
Jevtana is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) previously treated with a docetaxel-containing treatment regimen.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & 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 metastatic CRPC, as evidenced by disease progression despite bilateral orchiectomy or other androgen deprivation therapy (*see Appendix D*);
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a, b or c):
   a. Previously treated with a docetaxel-containing treatment regimen, unless not a candidate for or is intolerant of docetaxel;
   b. Member has small cell/neuroendocrine prostate cancer and Jevtana is prescribed in combination with carboplatin with concurrent steroid (off-label);
   c. Other category 1, 2A, or 2B NCCN-recommended uses not listed;
5. At the time of request, member has none of the following contraindications:
   a. Neutrophil counts of ≤ 1,500/mm^3;
   b. Severe hepatic impairment (total bilirubin > 3 × upper limit of normal);
6. Jevtana is prescribed concurrently with corticosteroid (*see Appendix E*);
7. Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy;
8. Requests meets one of the following (a or b):
   a. Dose does not exceed 25 mg/m^2 once every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 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 PA Health & Wellness benefit or the Continuity of Care policy (PA.PHARM.01) applies, or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. Jevtana is prescribed concurrently with corticosteroid (*see Appendix E*);
4. Member continues to use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy;
5. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 25 mg/m^2 once every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

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

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

III. Appendices

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CRPC: castration resistant prostate cancer
GnRH: gonadotropin-releasing hormone

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 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

- Contraindications:
  - Neutrophil counts of ≤ 1,500/mm^3
  - History of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80
  - Severe hepatic impairment (total bilirubin > 3x upper limit of normal
- Boxed warning(s): neutropenia and hypersensitivity

Appendix D: General Information

- CRPC is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (< 50 ng/dL). Per the NCCN, androgen deprivation therapy should be continued in the setting of CRPC while additional therapies are applied.
- Examples of androgen deprivation therapy include:
  - Bilateral orchiectomy (surgical castration)
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an anti-androgen:
    - LHRH agonists: Zoladex® (goserelin), leuprolide (Lupron Depot®, Eligard®), and Trelstar® (triptorelin)
    - Anti-androgens: bicalutamide (Casodex®), flutamide (Eulexin®), nilutamide (Nilandron®), Xtandi® (enzalutamide), Erleada® (apalutamide), Nubeqa® (darolutamide)
  - LHRH antagonists: Firmagon® (degarelix), Orgovyx™ (relugolix)

Appendix E: Concurrent Steroid Therapies

- Dexamethasone on the day of chemotherapy
- Prednisone daily

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CRPC	20 mg/m^2 IV every 3 weeks	25 mg/m^2 once every 3 weeks

V. Product Availability

Single-dose vial: 60 mg/1.5 mL

VI. References

1. Jevtana Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US LLC; May 2025. Available at: https://www.jevtanapro.com/. Accessed January 12, 2026.
2. Cabazitaxel Injection Prescribing Information. Princeton, NJ: Sandoz Inc.; January 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208715s000lbl.pdf. Accessed January 12, 2026.
3. Cabazitaxel. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium. Accessed January 27, 2026.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Ongcology: Prostate Cancer. Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed January 27, 2026.

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
J9064	Injection, cabazitaxel (sandoz), not therapeutically equivalent to J9043, 1 mg

Reviews, Revisions, and Approvals	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.	07/2018
2Q 2019 annual review: added prescriber requirement; references reviewed and updated.	04/2019
2Q 2020 annual review: added age limit; added requirement for concurrent steroid use; updated Section V dosing information to include 20 mg/m^2 dosing per prescribing information and NCCN; reviewed and updated.	04/2020
2Q 2021 annual review: allowed bypassing prior docetaxel if not a candidate for or are intolerant of docetaxel per NCCN; added that Jevtana continues to be prescribed with steroids; references reviewed and updated.	04/2021
2Q 2022 annual review: added requirement that "member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy" per NCCN and alignment with other prostate cancer clinical policies; removed pregnancy from contraindications per prescribing information; RT4: added new 60 mg/3 mL strength to product availability; references reviewed and updated.	04/2022
2Q 2023 annual review: no significant changes; RT4 – added 45 mg/4.5 mL and 60 mg/6 mL concentrations; updated *Appendix D* examples of androgen deprivation therapy per NCCN; removed 60 mg/3 mL dose form as product was discontinued; references reviewed and updated.	04/2023
2Q 2024 annual review: removed 45 mg/4.5 mL strength from Section VI; added HCPCS code [J9064]; references reviewed and updated.	04/2024
2Q 2025 annual review: added an additional bypass to required prior use of docetaxel-containing treatment regimen for members with small cell/neuroendocrine prostate cancer per NCCN Compendium; references reviewed and updated.	04/2025
2Q 2026 annual review: per NCCN compendium for off-label use in small cell/neuroendocrine prostate cancer clarified that Jevtana is prescribed in combination with carboplatin with concurrent steroid; revised initial approval duration from 6 to 12 months; references reviewed and updated.	04/2026