Clinical Policy: Cabazitaxel (Jevtana)

Reference Number: ERX.SPA.324
Effective Date: 06.01.19
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. 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 ≤ 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. 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).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Prostate Cancer (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Jevtana for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;

3. 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).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CRPC: castration resistant prostate cancer

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
- Contraindication(s):
  - 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)
  - Pregnancy
- Boxed warning(s): neutropenia and hypersensitivity

Appendix D: General Information
- Examples of androgen deprivation therapy include:
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an anti-androgen:
  - LHRH agonists: Zoladex® (goserelin), Vantas® (histrelin), leuprolide (Lupron Depot®, Eligard®), and Trelstar® (triptorelin)
  - Anti-androgens: bicalutamide (Casodex®), flutamide (Eulexin®), nilutamide (Nilandron®), Xtandi® (enzalutamide), Erleada® (apalutamide), Nubeqa® (darolutamide)
- LHRH antagonist: Firmagon® (degarelix)

Appendix E: Concurrent Steroid Therapies
- Dexamethasone on the day of chemotherapy
- Prednisone daily

V. Dosage and Administration

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

VI. Product Availability

Single-dose vial: 60 mg/1.5 mL

VII. References

1. Jevtana Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US LLC; January 2018. Available at: https://www.jevtanapro.com/. Accessed February 3, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 3, 2020.
3. Cabazitaxel. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 3, 2020.
4. National Comprehensive Cancer Network. Prostate Cancer Version 04.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 3, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.05.19	05.19
No significant change; updated Section V dosing information to include 20 mg/m^2 dosing per prescribing information and NCCN.	07.08.19	
2Q 2020 annual review: added requirement for concurrent steroid use; references reviewed and updated.	02.03.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.