

<b>Clinical Policy Title:</b>	cabazitaxel
<b>Policy Number:</b>	RxA.606
<b>Drug(s) Applied:</b>	Jevtana®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/07/2020
<b>Line of Business Policy Applies to:</b>	All lines of business

## Background

Cabazitaxel (Jevtana®) is a microtubule inhibitor.

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

## Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
cabazitaxel (Jevtana®)	Prostate cancer	20 or 25 mg/m <sup>2</sup> IV every 3 weeks with PO prednisone 10 mg administered daily throughout Jevtana® treatment.	25 mg/m <sup>2</sup> once every 3 weeks

## Dosage Forms

- Single-dose vial: 60 mg/1.5 mL

## Clinical Policy

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

### 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<sup>3</sup>;
  - b. Severe hepatic impairment (total bilirubin > 3 × upper limit of normal);
6. Jevtana® is prescribed concurrently with corticosteroid (see Appendix E);

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

7. Dose does not exceed 25 mg/m<sup>2</sup> once every 3 weeks.

**Approval duration**

**Commercial:** 6 months

**Medicaid:** 6 months

**II. Continued Therapy Approval**

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

1. Currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications 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, new dose does not exceed 25 mg/m<sup>2</sup> once every 3 weeks.

**Approval duration**

**Commercial:** 12 months

**Medicaid:** 12 months

**III. Appendices**

**APPENDIX A: Abbreviation/Acronym Key**

FDA: Food and Drug Administration

**APPENDIX B: Therapeutic Alternatives**

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Docetaxel	Androgen-deprivation therapy with docetaxel 75 mg/m <sup>2</sup> 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<sup>3</sup>
  - 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**

- Examples of androgen deprivation therapy include:
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an antiandrogen:
    - 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

**References**

1. Jevtana Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US LLC; March 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/201023s023lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/201023s023lbl.pdf) . Accessed September 23, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed September 23, 2020.
3. Cabazitaxel. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed September 23, 2020.
4. National Comprehensive Cancer Network. Prostate Cancer Version 02.2020. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf). Accessed September 23, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Clinical policy title was updated</li> <li>2. Line of business policy applies to was updated to All lines of business.</li> <li>3. Updated dosing information to add corticosteroid concurrent therapy.</li> <li>4. Initial approval criteria I.A was updated: updated diagnostic criteria, added corticosteroid concurrent therapy.</li> <li>5. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..."</li> <li>6. Updated Appendix C: removed pregnancy.</li> <li>7. Added Appendix D general information.</li> <li>8. Added Appendix E.</li> <li>9. Reference reviewed and updated.</li> </ol>	9/23/2020	12/07/2020