Clinical Policy Title:	cabazitaxel
Policy Number:	RxA.606
Drug(s) Applied:	Jevtana®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	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^2 intravenously every 3 weeks with oral prednisone 10 mg administered daily throughout Jevtana® treatment. **Mild hepatic impairment** (total bilirubin 1.1 to 1.5 times the upper limit of normal (ULN) or AST greater than 1.5 times the ULN): Administer cabazitaxel 20 mg/m2 intravenously. **Moderate hepatic impairment** (total bilirubin 1.6 to 3 times the ULN and any AST): Reduce the starting dose of cabazitaxel to 15 mg/m2 based on tolerability data. **Severe hepatic impairment** (total bilirubin greater than 3 times the ULN): Do not use cabazitaxel.	25 mg/m^2 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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. Dose does not exceed 25 mg/m^2 once every 3 weeks.

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is 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^2 once every 3 weeks.

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
AST: Aspartate aminotransferase
ULN: Upper limit of normal
CRPC: castration-resistant prostate cancer

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^2 for 6 cycles	Varies

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

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).

- 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; February 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/201023s023lbl.pdf . Accessed October 13, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed October 13, 2021.
3. Cabazitaxel. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed October 13, 2021.
4. National Comprehensive Cancer Network. Prostate Cancer Version 01.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 13, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated 2. Line of business policy applies to was updated to All lines of business.	9/23/2020	12/07/2020

3. Updated dosing information to add corticosteroid concurrent therapy. 4. Initial approval criteria I.A was updated: updated diagnostic criteria, added corticosteroid concurrent therapy. 5. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 6. Updated Appendix C: removed pregnancy. 7. Added Appendix D general information. 8. Added Appendix E. 9. Reference reviewed and updated.		
Policy was reviewed: 1. Dosing information was updated to include hepatic impairment doses adjustment. 2. Statement about provider sample "The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 3. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. Appendix A was updated to include abbreviations for ULN, AST and CRPC. 5. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the	10/13/2021	12/07/2021

drug is available by generic only". 6. References were reviewed and updated.		