RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Cabazitaxel (Jevtana)**
Policy Number: **RxA.606**
Drug(s) Applied: **Cabazitaxel (Jevtana®)**
Last Review Date: **03/2020**
Line of Business: **Commercial, Medicaid, HIM-Medical Benefit**

Background

Cabazitaxel (Jevtana®) is a microtubule inhibitor.

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.

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

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 prostate cancer;
2. Disease is hormone-refractory* and metastatic;
3. Prescribed by or in consultation with an oncologist or urologist;
4. Age ≥ 18 years;
5. Previously treated with a docetaxel-containing treatment regimen;
6. 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);
7. Dose does not exceed 25 mg/m^2 once every 3 weeks.

Approval duration: 6 months

II. Continued Therapy

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

1. Currently receiving medication via RxAdvance benefit, 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, new dose does not exceed 25 mg/m^2 once every 3 weeks.

Approval duration: 12 months

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

- 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

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 02.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 8, 2019.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	03/2020	03/06/2020