Clinical Policy: Cabazitaxel (Jevtana)

Reference Number: CP.PHAR.316
Effective Date: 02.01.17
Last Review Date: 11.17
Line of Business: Medicaid

Coding Implications
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 hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Jevtana is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of prostate cancer;
2. Disease is hormone-refractory* and metastatic;
3. Age ≥ 18 years;
4. Previously treated with a docetaxel-containing treatment regimen;
5. Jevtana is prescribed in combination with prednisone;
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

**Hormone-refractory prostate cancer indicates that disease has progressed despite androgen deprivation therapy (e.g., luteinizing hormone-releasing hormone [LHRH] agonists [e.g., leuprolide, goserelin], first-generation antiandrogens [e.g., nilutamide, flutamide], second-generation antiandrogens [e.g., enzalutamide], LHRH antagonists [e.g., degarelix]).*

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 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 Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no disease progression, no unacceptable toxicity);
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

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 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 – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prostate cancer	The individual dosage of Jevtana is based on calculation of the body surface area and is 25 mg/m^2 administered as a one-hour intravenous infusion every three weeks in combination with oral prednisone 10 mg administered daily throughout Jevtana treatment.	25 mg/m^2 once every 3 weeks

VI. Product Availability

Single dose vial: 60 mg/1.5 mL, supplied with diluent (5.7 mL)

VII. References

1. Jevtana Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US LLC; May 2017. Available at: https://www.jevtanapro.com/. Accessed August 21, 2017.
2. Jevtana Drug Monograph. Clinical Pharmacology. Accessed August 2017. http://www.clinicalpharmacology-ip.com.

3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 21, 2017.
4. National Comprehensive Cancer Network. Prostate Cancer Version 02.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 30, 2017.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.182 Excellus Oncology.	02.17	02.17
Converted to new template. Added age restriction as safety and effectiveness have not been established in pediatric patients per PI/safety approach. Removed requirement related to history of severe hypersensitivity reaction to cabazitaxel per safety approach.Added max dose per PI. Increased initial/continued approval from 3/6 months to 6/12 months, respectively. Re-auth: Added requirement that member is responding positively to therapy. Removed reasons to discontinue per safety approach-maintained no disease progression or unacceptable toxicity as examples of positive response to therapy.	08.30.17	11.17

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.