Clinical Policy: Cabazitaxel (Jevtana)

Reference Number: CP.PHAR.316
Effective Date: 03.01.17
Last Review Date: 05.21
Line of Business: HIM, 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 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.

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 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, unless not a candidate for or are intolerant of docetaxel;
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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is

NOT authorized): CP.PMN.53 for Medicaid and HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

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

1. Currently receiving medication via Centene 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. Jevtana is prescribed concurrently with corticosteroid (*see Appendix E*);
4. 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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM.PA.154 for health insurance marketplace.

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 policies – CP.PMN.53 for Medicaid and HIM.PA.154 for health insurance marketplace 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 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

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 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; December 2020. Available at: https://www.jevtanapro.com/. Accessed February 20, 2021.
2. Cabazitaxel. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium. Accessed February 20, 2021.

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
4Q 2018 annual review: added HIM Medical Benefit line of business; added COC; removed "prescribed in combination with prednisone" per NCCN prostate cancer guidelines ver 3.2018; references reviewed and updated.	07.31.18	11.18
2Q 2019 annual review: added prescriber requirement; references reviewed and updated.	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; revised HIM medical benefit to HIM line of business; references reviewed and updated.	02.03.20	05.20
2Q 2021 annual review: allowed bypassing prior docetaxel if not a candidate for or are intolerant of docetaxel per NCCN; added that Jevtana continues to be prescribed with steroids; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	02.20.21	05.21

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.