Clinical Policy: Cabazitaxel (Jevtana)

Reference Number: PA.CP.PHAR.316
Effective Date: 01/18
Last Review Date: 11/17

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for cabazitaxel for injection (Jevtana®).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® 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 castration-resistant prostate cancer;
2. Prescribed in combination with prednisone;
3. History of treatment with a docetaxel-containing regimen;
4. Member has none of the following contraindications:
   a. Neutrophil count ≤ 1,500/mm^3;
   b. History of severe hypersensitivity reaction (e.g., hypotension, bronchospasm, generalized rash/erythema) to cabazitaxel or to other drugs formulated with polysorbate 80;
   c. Severe hepatic impairment (i.e., total bilirubin > 3 times the upper limit of normal [ULN]).

_____

**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]).*

Approval duration: 3 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or the Continuity of Care policy (PA.LTSS.PHAR.01) applies, or member has previously met all initial approval criteria;
2. Member has none of the following reasons to discontinue:
   a. Disease progression or unacceptable toxicity;
   b. Neutrophil count ≤ 1,500/mm^3;
   c. History of severe hypersensitivity reaction (e.g., hypotension, bronchospasm, generalized rash/erythema) to cabazitaxel or to other drugs formulated with polysorbate 80;
   d. Severe hepatic impairment (i.e., total bilirubin > 3 times ULN);
   e. Grade 3* (serious) or Grade 4* (life-threatening) peripheral neuropathy.

**Grading is based on the Common Terminology Criteria for Adverse Events (CTCAE).*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Cabazitaxel is a microtubule inhibitor. Cabazitaxel binds to tubulin and promotes its assembly into microtubules while simultaneously inhibiting disassembly. This leads to the stabilization of microtubules, which results in the inhibition of mitotic and interphase cellular functions.

Formulations:

Jevtana is supplied as a kit consisting of the following:
- One single-dose vial of Jevtana injection as a viscous solution of 60 mg/1.5 mL in a clear glass vial.
- One single-dose vial of diluent for Jevtana as a solution of 13% (w/w) ethanol in water for injection in a clear glass vial.

FDA Approved Indications:

Jevtana is a microtubule inhibitor indicated:
- In combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Appendices

Appendix A: Abbreviation Key

CTCAE: Common terminology criteria for adverse events
LHRH: Luteinizing hormone-releasing hormone
ULN: Upper limit of normal

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	Approval Date

References

1. Jevtana prescribing information. Bridgewater, NJ: Sanofi-aventis U.S., LLC; October 2016. Available at http://products.sanofi.us/jevtana/jevtana.pdf. Accessed January 30, 2017.
2. Cabazitaxel. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 30, 2017.
3. Prostate cancer (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 30, 2017.