Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2020**
Policy Number: PA.CP.PHAR.316	**Effective Date: 01/2018** **Revision Date: 04/15/2020**
Policy Name: Cabazitaxel (Jevtana)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2020 annual review: added age limit; added requirement for concurrent steroid use; updated Section V dosing information to include 20 mg/m2 dosing per prescribing information and NCCN; reviewed and updated.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Cabazitaxel (Jevtana)

Reference Number: PA.CP.PHAR.316
Effective Date: 01/18
Last Review Date: 04/2020

Coding Implications
Revision Log

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 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 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. 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*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53

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 is responding positively to therapy;
3. 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*).

Approval duration: 12 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.PMN.53

III. Appendices

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
- Boxed warning: neutropenia and hypersensitivity
- Contraindications:
  - 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

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.

IV. Dosage and Administration

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

V. Product Availability

Single-dose vial: 60 mg/1.5 mL

VI. References

1. Jevtana Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US LLC; January 2018. Available at: https://www.jevtanapro.com/. Accessed February 3, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 3, 2020.
3. Cabazitaxel. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed Accessed February 3, 2020.
4. National Comprehensive Cancer Network. Prostate Cancer Version 04.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 3, 2020.

HCPCS Codes	Description
J9043	Injection, cabazitaxel, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: added COC; removed "prescribed in combination with prednisone" per NCCN prostate cancer guidelines ver 3.2018; references reviewed and updated.	07/18	

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2019 annual review: added prescriber requirement; references reviewed and updated.	04/19	
2Q 2020 annual review: added age limit; added requirement for concurrent steroid use; updated Section V dosing information to include 20 mg/m^2 dosing per prescribing information and NCCN; reviewed and updated.	04/2020	