



## Positive Quality Intervention: Cabazitaxel (Jevtana) For patients with Metastatic Castration-Resistant Prostate Cancer

**Description:** Cabazitaxel is indicated for treatment of patients with metastatic castration-resistant prostate (mCRPC) cancer previously treated with a docetaxel-containing treatment regimen in combination with prednisone.<sup>1</sup> The purpose of this PQI is to provide guidance for initiating cabazitaxel.

**Background:** Cabazitaxel was FDA approved in 2010 based on information from the phase 3 trial TROPIC that compared cabazitaxel plus prednisone to mitoxantrone in patients with mCRPC previously treated with a docetaxel-based treatment.<sup>2</sup> The recommended dose of cabazitaxel is now 20mg/m<sup>2</sup> every 3 weeks, the higher dose of 25mg/m<sup>2</sup> can be used at provider discretion for select patients.<sup>1,3</sup>

The CARD trial evaluated the use of cabazitaxel with prednisone/prednisolone and G-CSF for patients with mCRPC previously treated with docetaxel and an androgen- signaling -targeted inhibitor (abiraterone or enzalutamide) who had progressed within 12 months. The study compared cabazitaxel to initiation of another androgen- signaling -targeted inhibitor not previously used. The median radiographic progression-free survival was 8 months with cabazitaxel + prednisone/prednisolone + G-CSF and 3.7 months with abiraterone + prednisone/prednisolone or enzalutamide (HR 0.54, p<0.0001). When comparing median overall survival, cabazitaxel had a longer overall survival compared to androgen-signaling-targeted inhibitor, 13.6 months vs 11 months. Overall, cabazitaxel was associated with a 36% risk of death reduction. Secondary objectives of improvement in PFS, pain response, and time to symptomatic skeletal events favored cabazitaxel.<sup>1,4</sup>

### PQI Process:

- Review the medical record
  - Review past treatments for documentation of previous docetaxel administration
    - If docetaxel was not previously given, evaluate the reason for non-use. Per guidelines, patients who are not candidates for docetaxel can still be considered for cabazitaxel. (ex. pre-existing mild neuropathy prevented docetaxel use)<sup>5</sup>
  - Review labs for a recent CBC. Cabazitaxel is contraindicated in patients with neutrophil counts currently  $\leq 1,500$  cells/mm<sup>3</sup>.<sup>1</sup>
- Review treatment plan:<sup>1</sup>
  - Verify pre-medication orders:
    - Antihistamine: diphenhydramine 25 mg or equivalent antihistamine
    - Corticosteroid: dexamethasone 8 mg or equivalent steroid
    - H2 antagonist: famotidine 20 mg or equivalent H2 antagonist
  - Verify cabazitaxel dosing: 20 mg/m<sup>2</sup> administered every three weeks as a one-hour intravenous infusion
    - Dose adjustments needed for hepatic impairment; no adjustment necessary for renal impairment
  - If provider is starting dosing as 25 mg/m<sup>2</sup>, strongly consider G-CSF and CINV prophylaxis, incidence of grade 3-4 nausea at this dose was 2% and grade 3-4 vomiting was 2%<sup>1</sup>
  - Verify a prescription for prednisone has been entered

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### PQI Process continued:

- Verify a prescription or order for antiemetic: prophylaxis recommended as needed (PO or IV)
- Evaluate the need for primary prophylaxis with G-CSF
  - Recommended for patient with high-risk clinical features such as previous episodes of febrile neutropenia, older patients, extensive prior radiation, poor performance or nutritional status, or other serious comorbidities
- Monitoring<sup>1</sup>
  - CBC: baseline, weekly during cycle one, then before each treatment cycle
- Preparation<sup>1</sup>
  - Cabazitaxel requires two dilutions for preparation
  - Mix cabazitaxel vial with the entire contents of the included 5.7 mL diluent vial
  - Withdraw the patient specific dose of cabazitaxel
  - Inject dose into a 250 mL PVC-free container of 0.9% sodium chloride (NS) or 5% dextrose (D5W)
    - If dose is >65mg use a larger volume solution so the concentration is  $\leq 0.26$  mg/mL
  - Mix the final infusion solution by gently inverting the bag
- Administration<sup>1</sup>
  - IV over hour with a 0.22-µm nominal pore size inline filter

### Patient Centered Activities:

- Patient Education
  - Review the risk of infusion reactions, with cabazitaxel they are most likely to occur during first or second infusion. Signs of a reaction may include rash/itching, feeling dizzy, chest or throat tightness, breathing problems, face swelling
  - Instruct patient to report any adverse events, such as fever, diarrhea, nausea/vomiting, numbness/tingling of the hands or feet, or fatigue
  - Ensure patient has access to supportive medications
    - Anti-nausea (ex. 5-HT<sub>3</sub> receptor antagonist, metoclopramide, or prochlorperazine)
    - Anti-diarrheal (ex. loperamide)
  - Provide written information to patient on medication

### Supplemental Information:

- CareASSIST Patient Support Program<sup>6</sup>
  - Program can assist eligible patients with no insurance coverage or who lack coverage for the prescribed therapy
    - \*Medicare Part B patients with no supplemental insurance coverage may be eligible
- CareASSIST Copay Program<sup>5</sup>
  - Available to commercial insurance patient to help decrease out of pocket cost

### References:

1. Jevtana (cabazitaxel) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; December 2020
2. de Bono JS, Oudard S, Ozguroglu M, et al. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. *Lancet*. 2010;376(9747):1147-1154.
3. Eisenberger M, Hardy-Bessard AC, Kim CS, et al. Phase III Study Comparing a Reduced Dose of Cabazitaxel (20 mg/m<sup>2</sup>) and the Currently Approved Dose (25 mg/m<sup>2</sup>) in Postdocetaxel Patients With Metastatic Castration-Resistant Prostate Cancer-PROSELICA. *J Clin Oncol*. 2017;35(28):3198-3206.
4. de Wit R, de Bono J, Sternberg CN, et al. Cabazitaxel versus Abiraterone or Enzalutamide in Metastatic Prostate Cancer. *N Engl J Med*. 2019;381(26):2506-2518.
5. National Comprehensive Cancer Network. Prostate Cancer (Version 2.2020). [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf). Accessed August 22, 2020
6. CareASSIST by Sanofi Genzyme, <https://www.sanoficareassist.com/hcp/jevtana>.

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