

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 cancer (mCRPC) previously treated with a docetaxel-containing treatment regimen in combination with prednisone.¹ The purpose of this PQI is to provide guidance for initiating cabazitaxel.

Background: Cabazitaxel was FDA approved in 2010 based on the phase 3 trial TROPIC that compared cabazitaxel plus prednisone to mitoxantrone in patients with mCRPC previously treated with a docetaxel-based treatment.¹ The recommended dose of cabazitaxel is now 20mg/m² every 3 weeks. The higher dose of 25mg/m² can be used at provider discretion for select patients.^{2,3} 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 treatment group and 3.7 months with androgen receptor inhibitor group (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 progression free survival, pain response, and time to symptomatic skeletal events favored cabazitaxel.^{2,4}

PQI Process:²

- 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)⁵
 - Review labs for a recent CBC
 - Cabazitaxel is contraindicated in patients with neutrophil counts $\leq 1,500$ cells/mm³
- Review treatment plan:
 - Verify premedication 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/m² administered every three weeks as a one-hour intravenous infusion
 - Dose adjustments needed for hepatic impairment; no adjustment for renal impairment
 - If provider is starting dosing as 25 mg/m², 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%¹
 - Verify prescription for prednisone has been entered
 - Verify 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

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- Monitoring:
 - CBC: baseline, weekly during cycle one, then before each treatment cycle
- Preparation:
 - 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 >65 mg use a larger volume solution so the concentration is ≤ 0.26 mg/mL
 - Mix the final infusion solution by gently inverting the bag
- Administration:
 - IV over one hour with a 0.22-µm nominal pore size inline filter

Patient Centered Activities:

- Patient Education:
 - Review the risk of infusion reactions, which will most likely to occur during first or second infusion
 - Signs of a reaction may include rash/itching, dizziness, chest or throat tightness, difficulty breathing, 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-HT₃ receptor antagonist, metoclopramide, or prochlorperazine)
 - Anti-diarrheal (ex. loperamide)
 - Provide written information to patient on medication
- Patient Assistance: [NCODA Financial Assistance Tool](#)

References:

1. 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.
2. [Jevtana® \(cabazitaxel\) \[prescribing information\]](#).
3. Eisenberger M, Hardy-Bessard AC, Kim CS, et al. Phase III Study Comparing a Reduced Dose of Cabazitaxel (20 mg/m²) and the Currently Approved Dose (25 mg/m²) 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.

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