



Prior Authorization Approval Criteria

Jevtana (cabazitaxel)

Generic name:	cabazitaxel
Brand name:	Jevtana
Medication class:	antineoplastic
FDA-approved uses:	Treatment of hormone refractory metastatic prostate cancer in combination with prednisone previously treated with docetaxel containing treatment.
Available dosage forms:	one single use vial of Jevtana and one vial of diluent. 1.5ml vial contains 60mg of the drug.
Usual dose:	25mg/m ² administered every 3 weeks with prednisone 10mg administered daily throughout treatment. Patients should receive premedication with H2 antagonist and a corticosteroid.
Approximate cost: (based on AWP 2011)	One vial is \$6,400.00
Duration of therapy:	In clinical trials Jevtana was administered every 3 weeks for a maximum of 10 cycles.

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosed hormone refractory metastatic prostate cancer.
- Disease progression despite treatment with docetaxel (taxotere).
- Neutrophil count must be greater than 1,500 cells/mm³
- Must provide baseline liver function tests and renal function tests

Criteria for continuation of therapy:

- Patient responding to treatment without disease progression
- Patient tolerating treatment.
- Blood cell counts are being monitored frequently.

Caution:

- Black box warning
 - Neutropenia- deaths from neutropenia have been reported. Frequent blood cell counts are needed. Cabazitaxel should not be given to patients if neutrophil counts are $\leq 1,500/\text{mm}^3$
 - Hypersensitivity reactions including generalized rash or erythema, hypotension, and bronchospasm. Patients should receive premedication with H2 antagonist and a corticosteroid.
- GI symptoms can be severe, nausea, vomiting and severe diarrhea. Mortality related to diarrhea has been reported.
- Renal failure-fatal outcomes have been reported.
- Hepatic impairment- since cabazitaxel is extensively metabolized by the liver, the drug

should not be given to patients with hepatic impairment.

Monitoring:

- Frequent blood cell counts

Contraindication:

- Patients with a neutrophil count $\leq 1,500/\text{mm}^3$
- History of severe hypersensitivity reactions to cabazitaxel or to other drugs formulated with polysorbate 80.

Not approved if:

- Patient does not meet the above stated criteria
- Has a contraindication to the use of Jevtana
- Neutrophil counts $\leq 1,500/\text{mm}^3$
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Special considerations:

- Cabazitaxel is the first drug to be approved for prostate cancer that has progressed during or after therapy with docetaxel (Taxotere), but adverse effects can be severe.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/09/11