Jevtana (cabazitaxel)

Background
Jevtana is in the taxane class and acts by binding to tubulin and promoting its assembly into microtubules while inhibiting disassembly. This causes the stabilization of microtubules which in turn inhibits mitotic and interphase cellular functions. The drug is administered as a one hour intravenous infusion every three weeks in combination with 10 mg oral prednisone taken daily throughout the Jevtana treatment (1). Other potential strategies for treatment in the setting of post-docetaxel progression of prostate cancer include ixabepilone, mitoxantrone/prednisone, platinum agents, immunotherapies, and molecularly targeted agents (2).

Regulatory Status
FDA-approved indication: Jevtana is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen (1).

Jevtana carries a boxed warning for severe neutropenia Obtain frequent blood counts to monitor for neutropenia. Do not give Jevtana if neutrophil counts are ≤1,500 cells/mm3. Severe hypersensitivity can occur and may include generalized rash/erythema, hypotension and bronchospasm. To reduce the risk and/or severity of hypersensitivity of the infusion, the patient must be premedicated at least 30 minutes prior to each dose of Jevtana with an antihistamine, corticosteroid, and a H2 antagonist. Antiemetic prophylaxis is recommended and can be given
if needed. Jevtana is contraindicated if there is a history of severe hypersensitivity reactions to polysorbate 80. Jevtana should not be given to patients with hepatic impairment (1).

The safety and effectiveness of Jevtana have not been established in pediatric patients (1).

Related policies
Provenge, Xtandi, Zytiga

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Jevtana may be considered medically necessary in patients 18 years of age or more with hormone refractory metastatic prostate cancer who have been previously treated with a docetaxel containing treatment regimen and who will take Jevtana in combination with prednisone and whose neutrophil count >1500 cells/µL and bilirubin is within normal limits and ALT and/or AST are less than 1.5 times the upper limit of normal.

Jevtana is considered investigational in patients who are less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Hormone refractory metastatic prostate cancer

AND ALL of the following:
   a. Previously treated with a docetaxel containing treatment regimen
   b. Used in combination with prednisone
   c. Neutrophil count >1500 cells/µL and agreement to monitor during therapy
   d. NO hepatic impairment
      i. Bilirubin is not greater than or equal to upper limit of normal (ULN)
      ii. AST and/or ALT is not greater than or equal to 1.5 times the ULN
## Prior – Approval Requirements

### Age
18 years of age and older

### Diagnosis
Patient must have the following:

1. Hormone refractory metastatic prostate cancer

AND ALL of the following:

a. Using in combination with prednisone
b. Neutrophil count >1500 cells/µL and agreement to continue to monitor during therapy
c. Has NOT developed hepatic impairment
   i. Bilirubin is not above ULN
   ii. ALT and/or AST are less than 1.5 times ULN

### Policy Guidelines

#### Pre - PA Allowance
None

#### Prior - Approval Limits

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### Rationale

**Summary**

Jevtana is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. There are several potential patient safety concerns with treatment. Jevtana can cause serious side effects such as dangerously low neutrophil counts,
severe allergic reactions and kidney failure. Frequent and routine blood tests need to be monitored during treatment (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Jevtana while maintaining optimal therapeutic outcomes.

References

Policy History
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2012</td>
<td>New policy</td>
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<tr>
<td>December 2012</td>
<td>Annual review and update</td>
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<tr>
<td>March 2014</td>
<td>Annual editorial review and reference update.</td>
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<tr>
<td>September 2015</td>
<td>Addition of no hepatic impairment added to initiation of therapy</td>
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<tr>
<td>June 2016</td>
<td>Annual editorial review and reference update.</td>
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<tr>
<td>June 2017</td>
<td>Annual editorial review and reference update.</td>
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<tr>
<td>June 2017</td>
<td>Policy code changed from 5.04.27 to 5.21.27</td>
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<tr>
<td>June 2017</td>
<td>Addition of age limit to renewal criteria</td>
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Keywords
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 22, 2017 and is effective on July 1, 2017.