Medical Guideline Disclaimer

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LENGTH OF AUTHORIZATION

Coverage will be provided for 6 months and may be renewed.

DOsing LIMITS

Max Units (per dose and over time) [Medical Benefit]:

- 60 billable units per 21 days

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

Prostate Cancer †

- Patient is 18 years or older; AND

- Must be used in combination with a steroid (e.g. prednisone or dexamethasone); AND

- Patient has castration-resistant metastatic disease; AND

- Patient must have been previously treated with docetaxel; AND

- May not be used with other chemotherapy agents

† FDA Approved Indication(s)
II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

• Patient continues to meet criteria identified above; AND
• Disease response as defined by lack of disease progression, improvement in tumor size and/or improvement in patient symptoms; AND
• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: neutropenia, anemia, leukopenia, thrombocytopenia, severe hypersensitivity reactions, severe diarrhea, nausea, vomiting, severe hemorrhagic cystitis, renal or hepatic toxicity, interstitial lung disorders, etc.

Limitations/Exclusions
Jevtana is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9043</td>
<td>Injection, cabazitaxel, 1 mg: 1 billable unit= 1 mg</td>
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Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>00024-5824-xx</td>
<td>Jevtana 60 mg solution for injection</td>
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Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C61</td>
<td>Malignant neoplasm of prostate</td>
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<tr>
<td>Z85.46</td>
<td>Personal history of malignant neoplasm of prostate</td>
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</tbody>
</table>

Revision History

N/A

References

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cabazitaxel. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Prostate Cancer 2.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2018.