

1	<p><b>Treatment &amp; Condition</b></p> <p>Cabazitaxel for hormone-relapsed Castration resistant metastatic prostate cancer treated with docetaxel</p>																					
2	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance (TA391) May 2016</p> <p>Cabazitaxel (Jevtana<sup>®</sup>) in combination with prednisone or prednisolone is recommended as an option for treating metastatic hormone-relapsed prostate cancer in people whose disease has progressed during or after docetaxel chemotherapy, only if:</p> <ul style="list-style-type: none"> <li>the person has an eastern cooperative oncology group (ECOG) performance status of 0 or 1.</li> <li>the person has had 225 mg/m<sup>2</sup> or more of docetaxel</li> <li>treatment with cabazitaxel is stopped when the disease progresses or after a maximum of 10 cycles (whichever happens first)</li> <li>HSC trusts purchase cabazitaxel in pre-prepared intravenous-infusion bags, not in vials, and</li> <li>the company provides cabazitaxel with the discount agreed in the patient access scheme.</li> </ul> <p>Cabazitaxel is an additional therapeutic option, available alongside the existing range of NICE approved therapies (radium-223 dichloride, abiraterone, and enzalutamide) or best supportive care for people with metastatic hormone-relapsed prostate cancer treated with docetaxel.</p> <p>NICE published technology appraisal guidance on cabazitaxel in 2012 (TA255); it did not recommend cabazitaxel for hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen. Since then, additional evidence has been published and the company has agreed a new patient access scheme. Accordingly, NICE decided to update its guidance on cabazitaxel.</p>																					
3	<p><b>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</b></p> <table border="1" data-bbox="247 1646 1460 2094"> <thead> <tr> <th colspan="3" data-bbox="247 1646 1460 1780"><b>Annual number of people eligible for treatment in Northern Ireland after docetaxel chemotherapy</b></th> </tr> <tr> <th data-bbox="247 1780 1093 1848"><b>Population</b></th> <th data-bbox="1093 1780 1284 1848"><b>Proportion</b></th> <th data-bbox="1284 1780 1460 1848"><b>No. of people</b></th> </tr> </thead> <tbody> <tr> <td data-bbox="247 1848 1093 1892">Total population of NI</td> <td data-bbox="1093 1848 1284 1892"></td> <td data-bbox="1284 1848 1460 1892">1,840,498</td> </tr> <tr> <td data-bbox="247 1892 1093 1960">Estimated number of people diagnosed with prostate cancer in NI</td> <td data-bbox="1093 1892 1284 1960"></td> <td data-bbox="1284 1892 1460 1960">1,358</td> </tr> <tr> <td data-bbox="247 1960 1093 2027">Number of these who develop metastatic hormone-relapsed prostate cancer</td> <td data-bbox="1093 1960 1284 2027">15%</td> <td data-bbox="1284 1960 1460 2027">204</td> </tr> <tr> <td data-bbox="247 2027 1093 2072">Number of these who have treatment with docetaxel</td> <td data-bbox="1093 2027 1284 2072">50%</td> <td data-bbox="1284 2027 1460 2072">102</td> </tr> <tr> <td data-bbox="247 2072 1093 2094">Number of these eligible for subsequent chemotherapy</td> <td data-bbox="1093 2072 1284 2094">55%</td> <td data-bbox="1284 2072 1460 2094">56</td> </tr> </tbody> </table>	<b>Annual number of people eligible for treatment in Northern Ireland after docetaxel chemotherapy</b>			<b>Population</b>	<b>Proportion</b>	<b>No. of people</b>	Total population of NI		1,840,498	Estimated number of people diagnosed with prostate cancer in NI		1,358	Number of these who develop metastatic hormone-relapsed prostate cancer	15%	204	Number of these who have treatment with docetaxel	50%	102	Number of these eligible for subsequent chemotherapy	55%	56
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	<p>It is estimated that approximately 56 people annually in Northern Ireland would be eligible for treatment after docetaxel, of which cabazitaxel represents one option.</p> <p>However, it is the view of local clinicians that the expected volume of patients receiving cabazitaxel would be in the region of 5-6 per annum due to patients requiring a good performance status.</p> <p>It is assumed that approximately 17 patients will be treated with Abiraterone, 17 with Enzalutamide, 17 with Radium 223, and 6 with Cabazitaxel.</p>
4	<p><b>Patient Access Scheme availability</b></p> <p>The Department of Health and the manufacturers of cabazitaxel (Sanofi) have agreed that cabazitaxel will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence.</p> <p>NICE guidance assumes that the HSC orders the number of milligrams of cabazitaxel needed per patient and the company makes this available to the hospital in a compounded intravenous-infusion bag for each patient. Thus, the price of cabazitaxel is per milligram. NICE recommended cabazitaxel only if hospitals purchase compounded bags of cabazitaxel, because cabazitaxel would not be cost effective if the HSC were to purchase vials (because some cabazitaxel would be wasted, which increases the overall cost of treatment).</p>
5	<p><b>Costs</b> (<i>before PAS if applicable</i>)</p>
5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>Cabazitaxel, in combination with prednisone or prednisolone, is licenced for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.</p> <p>The recommended dose of cabazitaxel is 25mg/m<sup>2</sup> administered as a 1 hour intravenous infusion every 3 weeks in combination with oral prednisone or prednisolone 10mg administered daily throughout treatment.</p> <p>The list price of cabazitaxel is £3,696 per 60mg vial. Therefore the cost per milligram is £61.60.</p> <p>Assuming an average adult body surface area of 1.9m<sup>2</sup>, a dosage of 47.5mg every 3 weeks is required.</p> <p>Hence (before application of any PAS discount) the average cost per dose is £2,926. The average cost of 6 cycles is £17,556 per patient. The average cost of 10 cycles is £29,260 per patient.</p> <p>The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of cabazitaxel with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. In addition, Sanofi facilitates the supply of cabazitaxel in a pre-prepared (compounded) intravenous-infusion bag, containing the number of</p>

	<p>milligrams needed for each individual patient. The average cost of each cycle is commercial in confidence. The summary of product characteristics does not limit the number of cycles; the median number of cycles was six cycles in the key clinical trial, which capped cycles at ten cycles.</p>
<b>5.2</b>	<p><b>Infrastructure costs per patient per annum</b></p> <p>Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process.</p>
<b>5.3</b>	<p><b>Current in year costs</b></p> <p>The current in year costs will be covered via the cost per case arrangement.</p>
<b>5.4</b>	<p><b>Recurrent overall costs per annum</b> <i>(including additional costs)</i></p> <p>Recurrent costs <u>before</u> application of any PAS discounts for cabazitaxel (and also for alternative treatments):</p> <p>According to the Resource Impact Template that accompanies TA391, the net resource impact will be a cost of £7,000.</p>
<b>5.5</b>	<p><b>Opportunities for cost savings and how these will be secured</b></p> <p>Cost savings are not anticipated.</p>
<b>6</b>	<p><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>
<b>7</b>	<p><b>Commissioning arrangements</b></p> <p>This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis for a period of 12 months. After this time, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regime.</p>
<b>8</b>	<p><b>Monitoring arrangements</b></p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications.</p> <p>HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units.</p> <p>The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.</p>

**9**

**DHSSPS Legislative/Policy Caveats** *(NICE guidance only)*

This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.