

1	<p><b>Treatment &amp; Condition</b></p> <p>Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases</p>
2	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal Guidance TA412 (September 2016).</p> <p>Radium-223 dichloride is recommended as an option for treating hormone-relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases in adults, only if:</p> <ul style="list-style-type: none"> <li>• they have already had docetaxel or</li> <li>• docetaxel is contraindicated or is not suitable for them</li> </ul> <p>The drug is only recommended if the company provides radium-223 dichloride with the discount agreed in the patient access scheme.</p> <p>This guidance replaces TA376 and the previous cost estimates in that Service Notification should now be disregarded.</p>
3	<p><b>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</b></p> <p>According to the NICE Resource Impact Template that accompanies TA412, there will be 30 people per annum in Northern Ireland who will be eligible for treatment with radium-223.</p> <p>However, it is the view of local clinicians that this is an underestimation and that the number of people eligible for treatment under TA412 will be in the region of 60 per annum. This is supported by the number of cost per case requests received to date.</p>
4.	<p><b>Patient Access Scheme Availability</b></p> <p>The company that holds the marketing authorisation for radium-223 has agreed a patient access scheme with the Department of Health that makes radium-223 available with a discount applied to all invoices. The level of the discount is commercial in confidence.</p>
5.	<p><b>Costs (before PAS if applicable)</b></p>
5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>Radium-223 dichloride (Xofigo®) is a radiopharmaceutical agent designed to deliver alpha radiation to bone metastases without affecting normal bone marrow.</p> <p>The marketing authorisation for radium-223 dichloride (hereafter referred to as radium-223) is for the treatment of adults with castration-resistant prostate cancer,</p>

	<p>symptomatic bone metastases and no known visceral metastases'.</p> <p>Radium-223 dichloride is administered by intravenous injection at a recommended dose of 55 kBq/kg body weight every 4 weeks for 6 injections.</p> <p>Radium-223 is available at a radioactivity of 6.6 MBq in a 6-ml vial at a list price of £4,040 (excluding VAT). The manufacturer estimates the cost of a full course of treatment to be £24,240 per patient.</p> <p>The company that holds the marketing authorisation for radium-223 has agreed a patient access scheme with the Department of Health that makes radium-223 available with a discount applied to all invoices. The level of the discount is commercial in confidence.</p>
<b>5.2</b>	<p><b>Total Drug Costs per annum</b></p> <p><u>Current in year costs:</u> The in-year cost of treating 60 patients (before PAS discount) is approximately £0.72m.</p> <p><u>Recurrent costs:</u> The recurrent cost of treating 60 patients per year (before PAS discount) is £1.442m</p>
<b>5.4</b>	<p><b>Infrastructure costs 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>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 regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team</p>
<b>8.</b>	<p><b>Monitoring arrangements</b></p> <p>The HSCB 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>
<b>9.</b>	<p><b>DoH (NI) Legislative/Policy Caveats</b></p> <p>This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual</p>

<p>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.</p>
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