**HSCB Service Notification for the managed entry of new medicines and technologies**

| | |
|---|---|
| **1** | **Treatment & Condition**<br><br>Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases |
| **2** | **Associated appraisal body *&* Summary of ruling**<br><br>NICE Technology Appraisal guidance TA376. January 2016.<br><br>Radium‑223 dichloride (Xofigo®) is recommended as an option for treating adults with hormone‑relapsed prostate cancer, symptomatic bone metastases and no known visceral metastases, only if:<br>• they have had treatment with docetaxel, and<br>• the company provides radium‑223 dichloride with the discount agreed in the patient access scheme |
| **3** | **Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)*<br><br>Radium-223 dichloride is a treatment option in the second-line setting in people who have had docetaxel.<br><br>On the basis of cost per case applications received to date, it is estimated that 24 patients would be eligible for treatment with radium-223 annually.<br><br>However, it is the view of local clinicians that the expected volume of patients receiving radium-223 dichloride would be in the region of 50 – 60 patients per annum. The Board will closely monitor the uptake of radium to ascertain utilisation. |
| **4** | **Patient Access Scheme availability**<br><br>The company (Bayer) 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. |
| **5** | **Costs** *(before PAS if applicable)* |
| **5.1** | **Drug cost per patient per annum (for new and prevalent cases)**<br><br>Radium‑223 dichloride is a radiopharmaceutical agent designed to deliver alpha radiation to bone metastases without affecting normal bone marrow. The marketing authorisation for radium‑223 dichloride is 'for the treatment of adults with castration‑resistant prostate cancer, symptomatic bone metastases and no known visceral metastases'.<br><br>Radium‑223 is available at a radioactivity of 6 MBq in a 6ml vial at a net price of £4040 (excluding VAT). It is administered by intravenous injection at a |

| | |
|---|---|
| | recommended dose of 50 kBq/kg body weight every 4 weeks for 6 injections (giving an average cost of a course of treatment of £24,240, estimated by the company). The company (Bayer) 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. |
| **5.2** | **Infrastructure costs per patient per annum**<br><br>Any additional infrastructure costs associated with the introduction of new cancer therapies will be managed as part of the routine commissioning process. |
| **5.3** | **Current in year costs**<br><br>The current in year costs will be covered via the cost per case arrangement. |
| **5.4** | **Recurrent overall costs per annum** *(including additional costs)*<br><br>It is assumed that the 50 patients will be treated with the Radium-223 annually. The additional recurrent costs will be £1.125m (before PAS).<br><br>The patient numbers and expenditure on Radium 223 will be monitored and funding adjusted as required. |
| **5.5** | **Opportunities for cost savings and how these will be secured**<br><br>Cost-savings are not anticipated |
| **6** | **Expected implementation period**<br><br>There is no impediment to immediate implementation for new patients. |
| **7** | **Commissioning arrangements**<br><br>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. |
| **8** | **Monitoring arrangements**<br><br>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. This regimen will be administered in the Cancer Centre only.<br><br>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. |

| | |
|---|---|
| **9** | **DHSSPS Legislative/Policy Caveats**<br><br>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. |