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| 1.  | <p><b>Treatment &amp; Condition</b></p> <p>Everolimus for advanced renal cell carcinoma after previous treatment</p>   |
| 2.  | <p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA432 (22 February 2017)</p> <p>Everolimus is recommended within its marketing authorisation as an option for treating advanced renal cell carcinoma that has progressed during or after treatment with vascular endothelial growth factor targeted therapy, only if the company provides it with the discount agreed in the patient access scheme.</p>  |
| 3.  | <p><b>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</b></p> <p>NICE did not provide a resource impact template as access to this therapy was previously available in the Cancer Drugs Fund. However, everolimus is further option for treatment of advanced renal cell carcinoma in adults that has progressed during or after treatment with vascular endothelial growth factor therapy. Patient numbers are expected to be small. One cost per case request has been received to date.</p> <p>It is therefore expected that this guidance will not have significant impact on resources.</p> |
| 4.  | <p><b>Patient Access Scheme Availability</b></p> <p><b>(Yes/No)</b></p> <p>The company (Novartis) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of everolimus, with the discount applied at the point of purchase or invoice. 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>Everolimus is administered orally. The recommended dosage is 10 mg once daily, and treatment should continue as long as there is clinical benefit or until there are unacceptable adverse events.</p> <p>The price for a pack of 10mg everolimus tablets (30 tablets per pack) is £2,673 (excluding VAT). Hence the annual cost of treatment is £32,521.50 per patient at the list price.</p>   |

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| 5.2 | <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>  |
| 6.  | <p><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>   |
| 7.  | <p><b>Commissioning arrangements</b></p> <p>This regimen 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 regimen.</p>  |
| 8.  | <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.  | <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 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>   |