

1.	<p>Treatment & Condition</p> <p>Cabozantinib (Cabometyx®) for previously treated advanced renal cell carcinoma</p>																											
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance (TA463) August 2017</p> <p>Cabozantinib is recommended, within its marketing authorisation, as an option for treating advanced renal cell carcinoma in adults after vascular endothelial growth factor (VEGF)-targeted therapy, only if the company provides cabozantinib with the discount agreed in the patient access scheme.</p>																											
3.	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>Based on the assumptions made in the Resource Impact template that accompanies NICE TA463, the number of people in Northern Ireland expected to take up treatment with cabozantinib in line with NICE TA463 is as follows:</p> <table border="1" data-bbox="260 1032 1442 1742"> <thead> <tr> <th></th> <th>Percentage of previous row</th> <th>Number of people</th> </tr> </thead> <tbody> <tr> <td>Adult population of NI</td> <td></td> <td>1,417,588</td> </tr> <tr> <td>Incidence of kidney cancer</td> <td>0.021</td> <td>294</td> </tr> <tr> <td>People with kidney cancer who have renal cell carcinoma</td> <td>80</td> <td>235</td> </tr> <tr> <td>People with renal cell carcinoma diagnosed as advanced or metastatic</td> <td>38</td> <td>89</td> </tr> <tr> <td>People with advanced or metastatic renal cell carcinoma previously treated with systemic therapy</td> <td>75</td> <td>67</td> </tr> <tr> <td>People with previously treated advanced or metastatic renal cell carcinoma likely to have second-line treatment</td> <td>50</td> <td>34</td> </tr> <tr> <td>People estimated to have second line cabozantinib each year from year 2021/22</td> <td>26</td> <td>9</td> </tr> <tr> <td>People estimated to have third-line cabozantinib following treatment with Nivolumab</td> <td></td> <td>2</td> </tr> </tbody> </table>		Percentage of previous row	Number of people	Adult population of NI		1,417,588	Incidence of kidney cancer	0.021	294	People with kidney cancer who have renal cell carcinoma	80	235	People with renal cell carcinoma diagnosed as advanced or metastatic	38	89	People with advanced or metastatic renal cell carcinoma previously treated with systemic therapy	75	67	People with previously treated advanced or metastatic renal cell carcinoma likely to have second-line treatment	50	34	People estimated to have second line cabozantinib each year from year 2021/22	26	9	People estimated to have third-line cabozantinib following treatment with Nivolumab		2
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4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Ipsen) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of cabozantinib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>																											

5.	Costs (<i>before PAS if applicable</i>)
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The list price of cabozantinib is £5,143 per 30 tablet pack applicable to all dosages (20mg, 40 mg and 60 mg).</p> <p>Cabozantinib is administered orally at a dose of 60mg once daily. Hence, the cost per patient per annum (at the list price) is £62,576.17</p> <p>However, in studies, the median duration of treatment with cabozantinib was 8.3 months. The cost per patient for 8.3 months treatment with cabozantinib is approximately £43,281.85 (at the list price).</p>
5.2	<p>Infrastructure costs Per annum</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>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p>Commissioning arrangements</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>Monitoring arrangements</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>DoH (NI) Legislative/Policy Caveats</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>