

<p>1</p>	<p>Treatment & Condition <i>(Title)</i></p> <p>Axitinib for treating advanced renal cell carcinoma after failure of prior systemic treatment.</p>
<p>2</p>	<p>Associated appraisal body <i>(NICE/SMC/Other)</i> & Summary of ruling <i>(to include indication, restrictions, other relevant information)</i></p> <p>NICE technology appraisal guidance 333 (February 2015)</p> <p>Axitinib is recommended as an option for treating adults with advanced renal cell carcinoma after failure of treatment with a first-line tyrosine kinase inhibitor or a cytokine, only if the company provides axitinib with the discount agreed in the patient access scheme.</p> <p>At the time of publication of the NICE Technology Appraisal (February 2015), axitinib has a UK marketing authorisation only for use after failure with first-line sunitinib or a cytokine. If it is considered for use after any other first-line treatments, the prescriber should obtain and document informed consent and follow the relevant guidance published by the General Medical Council.</p> <p>Because the remit referred to NICE by the Department of Health for this technology appraisal applies to adults previously treated with a first-line tyrosine kinase inhibitor or a cytokine.</p>
<p>3</p>	<p>Number of people in Northern Ireland expected to take up service/therapy <i>(including new cases per year)</i></p> <p>Based on a pro rata calculation extrapolated from the Costing Statement that accompanies NICE TA333, there would be 50 people eligible for treatment under NICE TA333 however; it is unlikely that all these patients would take up treatment with axitinib.</p> <p>Since June 2014, axitinib was made available in Northern Ireland on a cost-per-case (CPC) basis following the positive outcome of an appraisal by the Scottish Medicines Consortium (SMC). Since June 2014 to July 2015, the HSC Board received 29 requests to fund the use of axitinib for the treatment of advanced renal cell carcinoma after failure of prior systemic treatment.</p> <p>This treatment will only be available at the NI Cancer Centre. Clinical advice suggests that there may be some variance between the NICE costing template and the local position.</p> <p>NICE assume that 65% of patients relapsing after sunitinib will be fit for second line treatment and that only 35% of these eligible patients will accept the treatment.</p>

	Local experience to date would suggest that approximately 67% of eligible patients accept treatment. Therefore the suggested patient numbers based on local knowledge would be approximately 33 patients per year with a range of between 24 and 34 patients. NICE suggests that the average dose will be 5.8 mg bd. Local advice suggests that the average dose is thought to be 7mg bd, though this may be less.																
4	<p>Patient Access Scheme availability</p> <p>The manufacturer of axitinib has agreed a patient access scheme with the Department of Health that makes axitinib available with a discount applied at the point of purchase or invoice. The size of the discount is commercial in confidence. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS.</p>																
5	Costs (before PAS if applicable)																
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Axitinib is available in 1mg, 3mg, 5mg and 7mg film-coated tablets at net prices of £703.40, £2110.20, £3517.00 and £4923.80 per 56-tablet pack respectively (excluding VAT). Axitinib is administered orally at a recommended starting dose of 5 mg twice daily. This dose may be increased to 7 mg and then up to 10 mg, or decreased to 3 mg and then down to 2 mg, depending on individual safety and tolerability.</p> <table border="1" data-bbox="298 1104 1390 1482"> <thead> <tr> <th colspan="2">Cost of treatment with axitinib in renal cell carcinoma*</th> </tr> <tr> <th>Dose</th> <th>Cost per patient per year</th> </tr> </thead> <tbody> <tr> <td>2mg twice daily</td> <td>£18,338.64</td> </tr> <tr> <td>3mg twice daily</td> <td>£27,507.64</td> </tr> <tr> <td>5mg twice daily</td> <td>£45,846.60</td> </tr> <tr> <td>7mg twice daily</td> <td>£64,185.25</td> </tr> <tr> <td>10mg twice daily</td> <td>£91,693.20</td> </tr> <tr> <td colspan="2">* List prices</td> </tr> </tbody> </table> <p>The Patient Access Scheme associated with TA333 provides axitinib at a confidential discount on the list price.</p>	Cost of treatment with axitinib in renal cell carcinoma*		Dose	Cost per patient per year	2mg twice daily	£18,338.64	3mg twice daily	£27,507.64	5mg twice daily	£45,846.60	7mg twice daily	£64,185.25	10mg twice daily	£91,693.20	* List prices	
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5.2	<p>Infrastructure costs per patient per annum</p> <p>There will be an opportunity for infrastructure issues to be reviewed on an annual basis.</p>																
5.3	<p>Current in year costs</p> <p>Gross in year costs are expected to be £744k as these patients have been treated since June 2014.</p>																

5.4	<p>Recurrent overall costs per annum (<i>including additional costs</i>)</p> <p>Assuming 24 patients prescribed 7mg and 5.8 cycles the gross recurrent cost will be £744k. (Before PAS)</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>There are currently no second-line drugs approved by NICE for treating advanced renal cell carcinoma after failure of first-line treatments. Therefore it is unlikely that implementation of NICE TA333 will result in any cost-savings.</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>Until recently, this regime has been made available on a CPC basis This was on the basis of a recommendation by the Scottish Medicines Consortium (SMC 855/13 November 2013).</p> <p>The service has suggested that there is likely variance between the NICE position on patient numbers and local experience and have suggested that patient numbers will be between a range of 24 and 33 patients per year., The HSCB will recurrently commission this regime on a basis at the lower level local estimate of 24 patients per year, 7mg dose for an average of 5.8 months.</p>
8	<p>Monitoring arrangements</p> <p>HSCB currently 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>DHSSPS 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>