

1.	<p>Treatment & Condition</p> <p>Lenvatinib with everolimus for previously treated advanced renal cell carcinoma</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA498 (January 2018)</p> <p>Lenvatinib plus everolimus is recommended as an option for treating advanced renal cell carcinoma in adults who have had 1 previous vascular endothelial growth factor (VEGF)-targeted therapy, only if:</p> <ul style="list-style-type: none"> • their Eastern Cooperative Oncology Group (ECOG) performance status score is 0 or 1 and • the company provides lenvatinib with the discount agreed in the patient access scheme
3.	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>According to the Resource Impact Template that accompanies NICE TA498, it is expected that 4 people in Northern Ireland will take up treatment with lenvatinib plus everolimus annually.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Eisai) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of lenvatinib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
5.	<p>Costs (before PAS if applicable)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The recommended daily dose of lenvatinib is 18mg (1×10mg capsule and 2×4mg capsules) once daily, with 5 mg of everolimus once daily.</p> <p>The list price of lenvatinib is £1,437 per 30-capsule pack (4mg and 10mg). The list price of everolimus is £2,250 per 30-tablet pack of 5mg everolimus.</p> <p>Hence, at list prices, the total cost of treatment with lenvatinib plus everolimus is:</p> <ul style="list-style-type: none"> • £6,561 per patient per month (30days) • £79,826 per patient per annum
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>