

1.	<p>Treatment & Condition</p> <p>Regorafenib for previously treated unresectable or metastatic gastrointestinal stromal tumours.</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA488 (November 2017)</p> <p>Regorafenib is recommended as an option for treating unresectable or metastatic gastrointestinal stromal tumours in adults whose disease has progressed on, or who are intolerant to, prior treatment with imatinib and sunitinib, only if:</p> <ul style="list-style-type: none"> • their Eastern Cooperative Oncology Group (ECOG) performance status is 0 to 1 and • the company provides regorafenib 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>By extrapolation from the Resource Impact Statement that accompanies TA488, NICE estimate that around 1-2 people per year in Northern Ireland are estimated to be eligible for treatment regorafenib for this indication. The view of local clinicians is that 2 – 3 patients per annum would be eligible for treatment under this NICE guidance.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Bayer) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of regorafenib, 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 dose of regorafenib is 160 mg (4 tablets of 40mg) taken once daily for 3 weeks followed by 1 week off therapy. This 4week period is considered a treatment cycle.</p> <p>The list price of regorafenib is £3,744 for 84 x 40mg tablets (excluding VAT).</p> <p>Hence, the cost of regorafenib at the list price for this indication is £3,744 per cycle</p> <p>Treatment should continue as long as benefit is observed or until unacceptable toxicity occurs.</p>

	<p>In trials, patients received an average of 8 cycles of treatment. Hence the total average cost of treatment is £29,952 per patient (excluding VAT)</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>