

1.	<p>Treatment & Condition</p> <p>Sorafenib (Nexavar[®]) for treating advanced hepatocellular carcinoma.</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA474 (September 2017)</p> <p>Sorafenib is recommended as an option for treating advanced hepatocellular carcinoma only for people with Child-Pugh grade A liver impairment, only if the company provides sorafenib within the agreed commercial access arrangement.</p>
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 TA474, in Northern Ireland it is expected that 37 people will be eligible for treatment with sorafenib each year (average duration of treatment = 5.3 months).</p> <p>However it is the view of local clinicians that this is an over estimation and the number of patients receiving treatment with sorafenib in line with this TA would be in the region of 20 – 25 patients per annum.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>NICE has indicated that the company (Bayer) has agreed a nationally available price reduction for sorafenib with the Commercial Medicines Unit. The details of this agreement are 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>Sorafenib is administered orally as 200mg film-coated tablets. The recommended dosage is 400mg twice daily (a total daily dose of 800mg). The summary of product characteristics recommends that treatment should be continued as long as clinical benefit is observed or until unacceptable toxicity occurs.</p> <p>The price for a pack of 200mg tablets (112 tablets per pack) is £3,575.56</p> <p>The cost per patient per annum is therefore £46,609.98 (at the list price). However, the average duration of treatment with sorafenib is 5.3 months therefore the average cost per patient per course, at the list price is £18,899.39</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>