

1	<p>Treatment & Condition</p> <p>Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer.</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal Guidance TA406 (September 2016).</p> <p>Crizotinib (Xalkori[®]) is recommended, within its marketing authorisation, as an option for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer in adults. The drug is recommended only if the company provides it 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>According to the NICE Resource Impact Template that accompanies TA406, it is estimated that 11 people will have treatment with crizotinib first-line annually in Northern Ireland.</p> <p>However, it is the view of local clinicians that the numbers predicted by the Resource Impact Template are high and that the expected volume of patients receiving crizotinib first line would be in the region of 6 per annum.</p>
4	<p>Patient Access Scheme availability</p> <p>The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of crizotinib, 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>Crizotinib is an inhibitor of the anaplastic lymphoma kinase (ALK) tyrosine kinase receptor and its variants. It has a marketing authorisation in the UK which includes 'the first-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC)'. The recommended dosage of crizotinib for this indication is 250 mg twice daily.</p> <p>The list price of crizotinib is £4,689 for 60 capsules. Thus, the annual cost per patient (before application of any PAS discount) is £51,579 (11 cycles per annum).</p>
5.2	<p>Infrastructure costs per patient 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>

5.3	<p>Current in year costs</p> <p>In year costs will depend on the number of cases treated. 5 cases will cost approximately £40,000.</p>
5.4	<p>Recurrent overall costs per annum <i>(including additional costs)</i></p> <p><u>Before</u> application of any PAS discounts and according to the Resource Impact Template that accompanies TA406, the financial impact of implementing this guidance is expected to be around £156,000 per year in Northern Ireland. It is anticipated that crizotinib will replace pemetrexed as first line treatment for a small cohort of patients and this may modify the net additional cost. Costs will be monitored via the cost per case mechanism.</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>Cost savings are not anticipated.</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 regime.</p>
8	<p>Monitoring arrangements</p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications.</p> <p>The HSCB routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across 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>