

1	<p><b>Treatment &amp; Condition</b></p> <p>Crizotinib for previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer</p>
2	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal Guidance TA422 (December 2016)</p> <p>Crizotinib is recommended, within its marketing authorisation, as an option for previously treated 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><b>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</b></p> <p>NICE did not provide a resource impact template providing an estimate of patient numbers. However, it is the view of local clinicians that approximately 2–3 patients per annum would be eligible for treatment in line with this TA.</p>
4.	<p><b>Patient Access Scheme Availability</b></p> <p><b>(Yes/No)</b></p> <p>The company (Pfizer) 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><b>Costs (before PAS if applicable)</b></p>
5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>Crizotinib (Xalkori®) has a marketing authorisation in the UK which includes 'adults with previously treated ALK-positive advanced non-small-cell lung cancer'.</p> <p>The recommended dosage of crizotinib is 250 mg, given orally, twice daily.</p> <p>The list price of crizotinib is £4,689 for 60 capsules (excluding VAT).</p> <p>Hence, at the list price, the cost of treatment is <b>£57,049.50 per patient per annum</b> assuming 12 months treatment.</p> <p>Advice from the local service suggests the average duration of treatment is 11 months. Based on 11 months treatment, the cost is anticipated to be £52,295.</p>

5.2	<p><b>Infrastructure costs Per annum</b></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><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p><b>Commissioning arrangements</b></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><b>Monitoring arrangements</b></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><b>DoH (NI) Legislative/Policy Caveats</b></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>