

1.	<p>Treatment & Condition</p> <p>Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia (CML).</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA425 (December 2016)</p> <p>Dasatinib and nilotinib are recommended as options for treating only chronic or accelerated-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults, if:</p> <ul style="list-style-type: none"> • they cannot have imatinib, or their disease is imatinib-resistant and • the companies provide the drugs with the discounts agreed in the relevant patient access schemes. <p>High-dose imatinib (that is, 600mg in the chronic phase or 800mg in the accelerated and blast-crisis phases) is not recommended for treating Philadelphia-chromosome-positive chronic myeloid leukaemia in adults whose disease is imatinib-resistant.</p> <p>TA425 is a review of TA241. Previously, in TA241 nilotinib was recommended (with a PAS discount) and dasatinib was not recommended.</p>
3.	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>As this is a review of TA241 and dasatinib is an alternative to treatment with nilitonib it is the view of local clinicians that the implementation of TA425 will not change current clinical practice and as such approximately 8-9 patients will be eligible for treatment with either therapy.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The manufacturers of dasatinib and nilotinib have agreed a patient access schemes with the Department of Health. These schemes provide a simple discount to the list price of dasatinib and nilotinib, with the discount applied at the point of purchase or invoice. The levels of the discounts 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><u>Dasatinib</u> The recommended starting dosage is 100mg orally once daily in the chronic phase or 140mg orally once daily in the accelerated and blast-crisis phase and treatment should continue until disease progression or until no longer tolerated by the</p>

	<p>patient.</p> <p>Dasatinib is available at a cost of £2,504.96 for both a pack of 30 x 100mg or 140mg tablets (excluding VAT). The cost of dasatinib treatment is £30,477.00 per year, assuming a treatment regimen of 100mg once daily or 140mg once daily. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of dasatinib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p> <p><u>Nilotinib</u></p> <p>The recommended starting dosage is 400mg twice daily for imatinib-resistant or intolerant CML in the chronic phase and 400mg twice daily in the accelerated phase and treatment should be continued as long as the patient continues to benefit.</p> <p>Nilotinib is available at a cost of £2,432.85 for a pack of 112 x 200mg tablets (excluding VAT). The cost of dasatinib treatment is £31,713.94 per year, assuming a treatment regimen of 100mg once daily or 140mg once daily. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of dasatinib, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</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. Nilotinib is already routinely commissioned for this indication under TA241. Dasatinib will be commissioned 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 treatment with dasatinib.</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</p>

	Specialist Services Commissioning Team for formal review and comment by the Team.
9.	DoH (NI) Legislative/Policy Caveats 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.