

1.	<p>Treatment & Condition</p> <p>Dasatinib, nilotinib and imatinib for <u>untreated</u> chronic myeloid leukaemia</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal Guidance TA426 (December 2016)</p> <p>Imatinib is recommended as an option for untreated, chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults.</p> <p>Dasatinib and nilotinib are recommended, within their marketing authorisations, as options for untreated chronic-phase Philadelphia-chromosome-positive chronic myeloid leukaemia in adults. The drugs are recommended only if the companies provide them with the discounts agreed in the relevant patient access schemes.</p> <p>TA426 is a review of TA251. Previously, in TA251, imatinib and nilotinib, with a patient access scheme, were recommended. 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 TA251 and dasatinib now represents a further treatment option for this patient population it is the view of local clinicians that the implementation of TA426 will not change current clinical practice and patient numbers should not change significantly from the current baseline.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The manufacturers of dasatinib and nilotinib have agreed 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> Dasatinib is administered orally. The recommended starting dosage is 100 mg once daily in the chronic phase and treatment should continue until disease progression or until no longer tolerated by the patient. Dose increase or reduction is recommended based on patient response and tolerability.</p> <p>Dasatinib is available at a list price of £2,504.96 for a pack of 30 x 100mg tablets (excluding VAT). The cost of dasatinib treatment is £30,477.00 per year, assuming a treatment regimen of 100 mg once daily once daily. The company has agreed a</p>

	<p>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>Imatinib</u> Imatinib is administered orally. The recommended starting dosage is 400 mg once daily in the chronic phase and treatment should be continued as long as the patient continues to benefit.</p> <p>Imatinib is available at a list price of £ £1,836.48 for 30 x 400mg tablets (excluding VAT) resulting in an annual cost of imatinib treatment of £22,343.84 per year assuming a treatment regimen of 400mg once daily.</p> <p><u>Nilotinib</u> Nilotinib is administered orally. The recommended starting dosage is 300 mg twice daily for newly diagnosed chronic-phase CML and treatment should be continued as long as the patient continues to benefit.</p> <p>Nilotinib is available at a list price of £2,432.85 for a pack of 112 x 150mg tablets (excluding VAT). The cost of nilotinib treatment is £31,715.00 per year, assuming a treatment regimen of 300 mg twice 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 nilotinib, 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. Imatinib and nilotinib are already routinely commissioned for this indication under TA251. 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 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>