

1	<p>Treatment & Condition</p> <p>Pegaspargase for treating acute lymphoblastic leukaemia.</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance [TA408] September 2016</p> <p>Pegaspargase, as part of antineoplastic combination therapy, is recommended as an option for treating acute lymphoblastic leukaemia in children, young people and adults only when they have untreated newly diagnosed disease.</p>
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>It is the view of local clinicians that approximately 15 patients per annum would be eligible for treatment in Northern Ireland.</p> <p>Pegaspargase has been in use in Northern Ireland as an unlicensed medicine for the treatment of acute lymphoblastic leukaemia in children and adults for a number of years. Expenditure for this therapy is already included in the quarterly Regional Use of Pharmacy Supplies in Oncology and Haematology report. It was granted a product licence in January 2016.</p> <p>It is the view of local clinicians that the implementation of NICE TA408 will not change current clinical practice.</p>
4	<p>Patient Access Scheme availability</p> <p>Not applicable</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>Pegaspargase (Oncaspar[®]) is indicated as 'a component of antineoplastic combination therapy in acute lymphoblastic leukaemia in paediatric patients from birth to 18 years, and adult patients'.</p> <p>Pegaspargase is administered as either an intramuscular injection or intravenous infusion.</p> <p><u>Paediatric patients and adults ≤21 years</u> The recommended dose of pegaspargase in patients with a body surface area ≥0.6m² and who are ≤21years of age is 2500IU (equivalent to 3.3ml pegaspargase)/m² body surface area every 14 days.</p> <p>Children with a body surface area <0.6m² should have 82.5IU (equivalent to 0.1ml pegaspargase)/kg body weight every 14 days.</p>

	<p><u>Adults >21 years</u></p> <p>Unless otherwise prescribed, the recommended posology in adults aged >21years is 2000 IU/m² every 14 days.</p> <p>The acquisition cost of pegaspargase is £1,296.19 per vial (ex VAT). One vial contains 3750IU.</p> <ul style="list-style-type: none"> • For paediatric and young adult patients, a course of pegaspargase costs between £5,144 (intermediate/standard-risk patients) and £15,246 (high-risk patients). • For adult patients, a course of pegaspargase costs between £6,034 (for those aged 41 years or over) and £7,544 (for those aged 40 years and under). <p>Costs are based on a dose of 1,000 IU/m² as used in clinical practice, which equates to 1 vial of pegaspargase per dose. Although the summary of product characteristics dose is higher (2,000 to 2,500IU/m²), only 1 vial would be used per treatment administration.</p>
<p>5.2</p>	<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>
<p>5.3</p>	<p>Current in year costs</p> <p>Expenditure for this therapy is already included in the quarterly Regional Use of Pharmacy Supplies in Oncology and Haematology report. It was granted a product licence in January 2016.</p> <p>It is the view of local clinicians that the implementation of NICE TA408 will not change current clinical practice. Given that this therapy is already funded within the baseline it is anticipated that no additional funding will be required.</p> <p>However, a cost per case mechanism will be used initially to estimate recurrent demand.</p>
<p>5.4</p>	<p>Recurrent overall costs per annum (including additional costs)</p> <p>According to the Resource Impact Statement that accompanies TA408, it is not expected that this guidance will have an impact on resources. This is because it is thought that practice will not substantially change as a result of this guidance.</p> <p>Pegaspargase is the current standard of care for people with untreated, newly diagnosed, acute lymphoblastic leukaemia and is already included in baseline commissioning.</p> <p>This technology only recently obtained a licence for this condition. Local clinical opinion is that 15 patients will require treatment. Given the estimated small number and NICE advice of no change in resources, a CPC mechanism will be used initially to estimate recurrent demand.</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 drug is already commissioned and in the baseline.</p>
8	<p>Monitoring arrangements</p> <p>The HSCB routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs from the Cancer Centre and other units.</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>