

<p>1.</p>	<p><b>Treatment &amp; Condition</b></p> <p>Blinatumomab for previously treated Philadelphia-chromosome-negative acute lymphoblastic leukaemia</p>
<p>2.</p>	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA450 (June 2017)</p> <p>Blinatumomab is recommended within its marketing authorisation as an option for treating Philadelphia-chromosome-negative relapsed or refractory precursor B-cell acute lymphoblastic leukaemia in adults, only if the company provides it with the discount agreed in the patient access scheme.</p>
<p>3.</p>	<p><b>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</b></p> <p>The resource impact statement that NICE published to accompany this TA indicates that the estimated number of people treated with blinatumomab in England per year will be less than 50.</p> <p>Hence, pro rata, it is expected that 1-2 people in Northern Ireland will be treated with blinatumomab per year.</p>
<p>4.</p>	<p><b>Patient Access Scheme Availability</b></p> <p><b>(Yes/No)</b></p> <p>The company (Amgen) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of blinatumomab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
<p>5.</p>	<p><b>Costs (before PAS if applicable)</b></p>
<p>5.1</p>	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>Patients may have 2 cycles of treatment. A single cycle of treatment is 28 days (4 weeks) of continuous infusion. Each cycle of treatment is separated by a 14 day (2 week) treatment-free interval.</p> <p>Patients who experience complete remission after 2 treatment cycles may have up to 3 additional cycles of consolidation treatment, based on an individual benefits-risks assessment.</p> <p>Blinatumomab is administered at a dose of 9 micrograms per day for the first 7 days of the first cycle. All doses after that are 28 micrograms per day.</p> <p>At the list price, blinatumomab costs £2,017 per 38.5microgram vial.</p>

Dosing and costs			
Cycle 1		2 week-treatment free interval  (Days 29 – 42)	Cycle 2 and subsequent cycles (Days 1 - 28)
Starting dose Days 1 - 7	Subsequent dose Days 8 - 28		28 mcg/day via continuous infusion
9 mcg/day via continuous infusion	28 mcg/day via continuous infusion		Uses 784micrograms per cycle (21 vials) = £42,357
Uses 63micrograms in total (2 vials) = £4,034	Uses 588micrograms in total (16 vials) = £32,272		
<p>Thus, the cost per patient for patients who have:</p> <ul style="list-style-type: none"> <li>• 2 cycles only = £78,633 in total</li> <li>• 2 initial cycles + 3 consolidation cycles = £205,704 in total</li> </ul>			
<b>5.2</b>	<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>		
<b>6.</b>	<p><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>		
<b>7.</b>	<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 regimen.</p>		
<b>8.</b>	<p><b>Monitoring arrangements</b></p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications. 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>		
<b>9.</b>	<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>		