

1.	<p><b>Treatment &amp; Condition</b></p> <p>Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years.</p>
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA554 (December 2018)</p> <p>Tisagenlecleucel therapy (Kymriah<sup>®</sup>) is recommended for use within the Cancer Drugs Fund as an option for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years, only if the conditions in the managed access agreement are followed.</p>
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b></p> <p>By extrapolation from the NICE Resource Impact Statement that accompanies this guidance, it is estimated that 1 person per year in Northern Ireland with relapsed or refractory B-cell acute lymphoblastic leukaemia will be eligible for treatment with tisagenlecleucel in line with this guidance.</p>
4.	<p><b>Patient Access Scheme Availability</b></p> <p>(<u>Yes/No</u>)</p> <p>The company (Novartis) has a commercial arrangement. This makes tisagenlecleucel available to the NHS with a discount. The size of the discount is commercial in confidence.</p>
5.	<p><b>Infrastructure Requirements</b></p> <p>The additional infrastructure requirements associated with this treatment are likely to be substantial. HSCB Commissioners will work with Specialist Centres in GB to estimate these costs.</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. Thereafter, 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.</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>
<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> <p>The Rural Needs Act (NI) 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the Act.</p>