

1.	<p><b>Treatment &amp; Condition</b></p> <p>Gilteritinib for treating relapsed or refractory acute myeloid leukaemia</p>																		
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA642 (August 2020)</p> <p>Gilteritinib (Xospata<sup>®</sup>) monotherapy is recommended as an option for treating relapsed or refractory FLT3-mutation-positive acute myeloid leukaemia (AML) in adults only if the company provides gilteritinib according to the commercial arrangement.</p> <p>Gilteritinib should not be given as maintenance therapy after a haematopoietic stem cell transplant.</p>																		
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b></p> <p>According to the NICE Resource Impact Template that accompanies NICE TA642, patient numbers are estimated as follows:</p> <table border="1" data-bbox="220 1070 1439 1223"> <thead> <tr> <th colspan="6">Estimated number of people in Northern Ireland receiving gilteritinib</th> </tr> <tr> <th></th> <th>2020/21</th> <th>2021/22</th> <th>2022/23</th> <th>2023/24</th> <th>2024/25</th> </tr> </thead> <tbody> <tr> <td>Population receiving gilteritinib each year</td> <td>6</td> <td>11</td> <td>11</td> <td>11</td> <td>11</td> </tr> </tbody> </table>	Estimated number of people in Northern Ireland receiving gilteritinib							2020/21	2021/22	2022/23	2023/24	2024/25	Population receiving gilteritinib each year	6	11	11	11	11
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4.	<p><b>Patient Access Scheme Availability</b></p> <p>(<u>Yes</u>/No)</p> <p>The company (Astellas Pharma) has a commercial arrangement. This makes gilteritinib 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>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>	<b>Monitoring arrangements</b>  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.  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.
<b>9.</b>	<b>DoH (NI) Legislative/Policy Caveats</b>  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.