

1.	<p>Treatment & Condition</p> <p>Liposomal cytarabine–daunorubicin for untreated acute myeloid leukaemia</p>																		
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA552 (December 2018)</p> <p>Liposomal cytarabine–daunorubicin (Vyxeos[®]) is recommended, within its marketing authorisation, as an option for untreated therapy-related acute myeloid leukaemia or acute myeloid leukaemia with myelodysplasia-related changes in adults. It is recommended only if the company provides it according to the commercial arrangement.</p>																		
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>By extrapolation from the Resource Impact Statement that accompanies NICE TA552, numbers of people expected to take up treated with this therapy in line with this guidance are as follows:</p> <table border="1" data-bbox="261 1032 1441 1330"> <thead> <tr> <th colspan="6">Estimated number of people in Northern Ireland having liposomal cytarabine–daunorubicin</th> </tr> <tr> <th></th> <th>2018/19</th> <th>2019/20</th> <th>2020/21</th> <th>2021/22</th> <th>2022/23</th> </tr> </thead> <tbody> <tr> <td>Population having liposomal cytarabine–daunorubicin each year</td> <td><1</td> <td>6</td> <td>6</td> <td>6</td> <td>6</td> </tr> </tbody> </table>	Estimated number of people in Northern Ireland having liposomal cytarabine–daunorubicin							2018/19	2019/20	2020/21	2021/22	2022/23	Population having liposomal cytarabine–daunorubicin each year	<1	6	6	6	6
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4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Jazz Pharmaceuticals) has a commercial arrangement. This makes liposomal cytarabine–daunorubicin available to the NHS with a discount. The size of the discount is commercial in confidence.</p>																		
5.	<p>Infrastructure Requirements</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>																		

<p>7.</p>	<p>Commissioning arrangements</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>
<p>8.</p>	<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>
<p>9.</p>	<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> <p>The <i>Rural Needs Act (NI) 2016</i> 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>