

<p>1.</p>	<p>Treatment & Condition</p> <p>Obinutuzumab with bendamustine for treating follicular lymphoma refractory to rituximab</p>
<p>2.</p>	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA472 (August 2017)</p> <p>Obinutuzumab (Gazyvaro[®]) in combination with bendamustine followed by obinutuzumab maintenance is recommended for use as an option for treating adults with follicular lymphoma that did not respond or progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen, only if the conditions in the managed access agreement for obinutuzumab are followed.</p>
<p>3.</p>	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>According to the NICE Resource Impact Statement that accompanies TA472, it is expected that 470 people in England will take up treatment with obinutuzumab annually.</p> <p>Extrapolated to the Northern Ireland population, this equates to 16 people per year in Northern Ireland who will take up treatment with obinutuzumab.</p> <p>In a similar SMC appraisal, the submitting company estimated there would be 74 patients eligible for treatment with obinutuzumab-bendamustine in all years. The estimated uptake rate was 10% in year 1 (7 patients) rising to 50% in year 5 (37 patients). Extrapolated to the Northern Ireland population, this equates to 3 patients in year 1 and 13 by year 5.</p>
<p>4.</p>	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Roche) has a managed access arrangement. This makes obinutuzumab available to the NHS with a discount. The size of the discount is commercial in confidence.</p> <p>HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the managed access arrangement.</p>
<p>5.</p>	<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>
<p>6.</p>	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>

7.	<p>Commissioning arrangements</p> <p>This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team on a cost-per-case (CPC) basis for as long as NICE indicates that funding via the Cancer Drugs Fund is appropriate.</p>
8.	<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 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>Numbers of patients who received or are receiving treatment will be monitored by the HSC Board and reported to the Department of Health.</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> <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>