

1.	<p>Treatment & Condition</p> <p>Daclizumab for treating relapsing–remitting multiple sclerosis</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA441 (April 2017)</p> <p>Daclizumab is recommended as an option for treating multiple sclerosis in adults, only if:</p> <ul style="list-style-type: none"> • the person has active relapsing–remitting multiple sclerosis previously treated with disease-modifying therapy, or rapidly evolving severe relapsing–remitting multiple sclerosis (that is, at least 2 relapses in the previous year and at least 1 gadolinium-enhancing lesion at baseline MRI) and • alemtuzumab is contraindicated or otherwise unsuitable and • the company provides the drug with the discount agreed in the patient access scheme.
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>The Resource Impact Template that accompanies NICE TA441 indicates that the implementation of this guidance is not expected to have a significant impact on resources or projected patient numbers. This therapy is an additional treatment option for patients with this condition.</p>
4.	<p>Patient Access Scheme Availability (<u>Yes</u>/No)</p> <p>The company (Biogen Idec) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of daclizumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
5.	<p>Costs (<i>before PAS if applicable</i>)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Daclizumab (Zinbryta[®]) is given as a 150mg subcutaneous injection once monthly. The list price is £1,597 per pre-filled pen containing 150 mg daclizumab.</p> <p>Therefore, the annual cost per patient (at the list price) = £1597 x 12 = £19,160.04</p> <p>The company (Biogen Idec) has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of daclizumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>

5.2	<p>Infrastructure costs per annum</p> <p>It is anticipated that infrastructure requirements will be minimal.</p> <p>Infrastructure requirements for the delivery of all Disease Modifying Therapies (DMTs) for MS are reviewed annually as part of routine commissioning arrangements for supporting growth in the provision of these therapies.</p>
6.	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p>Commissioning arrangements</p> <p>This drug will be formally commissioned by HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis.</p>
8.	<p>Monitoring arrangements</p> <p>The HSC Board has robust arrangements in place for the monthly monitoring of all DMTs (patient numbers, costs and waiting times). This regime will be included within the monitoring information.</p> <p>Monitoring returns are reviewed by the Specialist Services Commissioning Team each month.</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>