

1	<p>Treatment & condition</p> <p>Alemtuzumab for treating adults with relapsing–remitting multiple sclerosis</p>
2	<p>Associated appraisal body & summary of ruling <i>(to include indication, restrictions, other relevant information)</i></p> <p>NICE Technology Appraisal Guidance 312 (May 2014)</p> <p>Alemtuzumab is recommended as an option, within its marketing authorisation, for treating adults with active relapsing–remitting multiple sclerosis (RRMS).</p>
3	<p>Number of people in Northern Ireland expected to take up service/therapy <i>(including new cases per year)</i></p> <p>At the end of March 2014, there were a total of 1,456 patients in Northern Ireland on DMTs. It is anticipated that as in previous years there will be net increase of around 100 patients accessing therapies in Northern Ireland during 2014/15. This increase will be across the range of therapies available including any new therapies approved during 2014/15. The availability of alemtuzumab will offer the option of an additional therapy for clinicians to consider in treating patients.</p> <p>The NICE guidance for TA312 indicates that over a five year period up to 24% of patients currently on treatment (circa 350) would be eligible to switch to alemtuzumab. This would equate to a cost of £1.7m at year five. Discussion with local clinicians has indicated that the anticipated use of alemtuzumab will be low with projected uptake of up to 5 patients in 2014/15.</p> <p>It is not possible at this point to definitively predict the number of patients in future years. However, clinicians do not expect a significant uptake in the use of this therapy and the financial assumptions used are based on 5 patients commencing on treatment per annum.</p>
4	<p>Patient Access Scheme availability</p> <p>Not applicable</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>The recommended dosage of alemtuzumab is 12 mg/day administered by intravenous infusion for 2 treatment courses. The initial treatment course lasts 5 consecutive days, followed 12 months later by the second treatment course of 3 consecutive days.</p> <p>The price of alemtuzumab is £7045 per 12 mg vial, which equates to £56,360 for the full course of treatment consisting of 5 daily consecutive 12 mg doses in year 1 (£35,225), followed by 3 daily consecutive 12 mg doses 12 months later in year 2 (£21,135). These costs need to be offset against the cost of existing patient treatments.</p>

<p>5.2</p>	<p>Infrastructure costs per patient per annum</p> <p>The use of this therapy requires more intensive patient monitoring. The costs of administration and testing are in the region of £3,000 per patient commenced on treatment.</p>																		
<p>5.3</p>	<p>Current in year costs</p> <p>The 2014/15 net costs associated with commencing five patients on treatment will be £152k. The projected profile of additional costs for 5 additional patients started each year over a five year period from 2014/15 is set out in the table below.</p> <table border="1" data-bbox="240 667 1489 775"> <thead> <tr> <th></th> <th>2014/15</th> <th>2015/16</th> <th>2016/17</th> <th>2017/18</th> <th>2018/19</th> </tr> </thead> <tbody> <tr> <td>Total Costs</td> <td>£152k</td> <td>£228k</td> <td>£192k</td> <td>£155k</td> <td>£119k</td> </tr> <tr> <td>Additional Costs</td> <td>£152k</td> <td>£77k</td> <td>£(36k)</td> <td>£(36k)</td> <td>£(36k)</td> </tr> </tbody> </table>		2014/15	2015/16	2016/17	2017/18	2018/19	Total Costs	£152k	£228k	£192k	£155k	£119k	Additional Costs	£152k	£77k	£(36k)	£(36k)	£(36k)
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<p>5.4</p>	<p>Recurrent overall costs per annum <i>(including additional costs)</i></p> <p>As outlined in the table above, on the basis of the projected numbers discussed with clinical colleagues, additional funding is required in 2014/15 and 2015/16. Following this the recurrent requirements reduce by approximately £36k per annum for 3 years.</p>																		
<p>5.5</p>	<p>Opportunities for cost savings and how these will be secured</p> <p>It is not anticipated that there will be cost savings associated with the introduction of this treatment. The costs of current DMTs for those patients already on treatments will offset the total requirements of introducing alemtuzumab.</p>																		
<p>6</p>	<p>Expected implementation period</p> <p>It is expected that this therapy will be available for use in Northern Ireland in quarter three of 2014/15. The introduction will be subject to confirmation of the level of funding available and submission of an IPT by Belfast Trust. For patients being considered for drug treatment for RRMS, it is expected that alemtuzumab be considered as an option for treatment alongside the currently available disease modifying therapies (DMTs). Alemtuzumab will be introduced on a cost per case basis and individual requests will be signed off by the MS Specialist Interest Group (Trust clinicians).</p>																		
<p>7</p>	<p>Commissioning arrangements</p> <p>This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team on a cost-per-case (CPC) basis.</p> <p>The treatment will be commissioned through the existing Investment Proposal Templates and subsequent negotiation process as part of the overall commissioning arrangements for the suite of MS drugs.</p> <p>An investment proposal template will be completed by the BHSCT and the final profile of resources and monitoring arrangements agreed.</p>																		

8	Monitoring arrangements The extant monthly monitoring return will be amended to capture patient commencement, suspension and cessation on this regime. This is reviewed monthly by the Specialist Service Commissioning Team. The Specialist Services Commissioning Team has an established sub group on MS drugs with clinical and managerial representation from the MS service team. This group reviews all aspects of MS acute and drug regime therapy on an ongoing basis.
9	DHSSPS Legislative/Policy Caveats (<i>NICE guidance only</i>) 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.