

1	<p>Treatment & Condition</p> <p>Dimethyl fumarate for treating relapsing-remitting multiple sclerosis.</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal Guidance 320 (August 2014)</p> <p>Dimethyl fumarate is recommended as an option for treating adults with active relapsing-remitting multiple sclerosis (RRMS) (normally defined as 2 clinically significant relapses in the previous 2 years), only if:</p> <ul style="list-style-type: none"> • they do not have highly active or rapidly evolving severe relapsing-remitting multiple sclerosis, and • the manufacturer provides dimethyl fumarate with the discount agreed in the patient access scheme(PAS)
3	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>At the end of October 2014, there were a total of 1,486 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 dimethyl fumarate will offer the option of an additional therapy for clinicians to consider in treating patients. Alternative treatment options for the population that dimethyl fumarate is recommended for in the guidance include teriflunomide, beta interferons and glatiramer acetate.</p> <p>The costing template for NICE TA320 indicates that up to 39% of people with relapsing-remitting multiple sclerosis would be eligible for treatment with dimethyl fumarate. This equates to up to 600 patients in Northern Ireland.</p> <p>MS clinicians have indicated that discussions would be required with patients during review appointments about commencing on or transferring to dimethyl fumarate to confirm clinical suitability. During the 2014/15 the anticipated uptake is 110 patients. The number of patients accessing this therapy will increase further from 2015/16 and beyond in line with NICE projections.</p>
4	<p>Patient Access Scheme availability</p> <p>The manufacturer of dimethyl fumarate has agreed a patient access scheme with the Department of Health, with a simple discount applied at the point of purchase or invoice. The level of discount is commercial in confidence.</p>

5	Costs <i>(before PAS if applicable)</i>																																								
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Dimethyl fumarate is taken orally. The recommended dosage is 120 mg twice daily in the first week of treatment and 240 mg twice daily thereafter. The prices of a pack of 120-mg tablets (14 tablets per pack) and 240-mg tablets (56 tablets per pack) are £343 and £1,373 respectively (excluding VAT; BNF68)</p> <p>Assuming that the drug is prescribed as above, cost per patient per year = £17,849 (before application of PAS discount). . The majority of patients commencing on this therapy in-year will already be receiving other DMTs. The net additional cost per patient per annum is £10,172 (before application of PAS discount).</p>																																								
5.2	<p>Infrastructure costs per patient per annum</p> <p>It is recognised from the NICE guidance that there may be some infrastructure requirements particularly in respect of blood monitoring. The HSC Board does not anticipate that this will be a significant resource and will work with clinicians to identify how the requirements compare to current infrastructure needs of new patients commencing on injectable therapies.</p>																																								
5.3	<p>Current in year costs</p> <p>Clinicians have indicated that around 110 patients will commence on this therapy between October 2014 and March 2015. As outlined above, the majority of patients commencing on this therapy in-year will already be receiving other DMTs.</p> <p>On the basis of an uptake of around 18 patients per month (Oct 2014 – March 2015) at a cost of £848 per month per patient (to include an offset of the current costs), the anticipated in-year cost of introducing this therapy is around £321,000 (before application of PAS discount).</p> <table border="1" data-bbox="240 1360 1214 1759"> <thead> <tr> <th></th> <th>Months</th> <th>Patients</th> <th>Cost per month</th> <th>Cost</th> </tr> </thead> <tbody> <tr> <td>Oct</td> <td>6</td> <td>18</td> <td>£848</td> <td>£91,584</td> </tr> <tr> <td>Nov</td> <td>5</td> <td>18</td> <td>£848</td> <td>£76,320</td> </tr> <tr> <td>Dec</td> <td>4</td> <td>18</td> <td>£848</td> <td>£61,056</td> </tr> <tr> <td>Jan</td> <td>3</td> <td>18</td> <td>£848</td> <td>£45,792</td> </tr> <tr> <td>Feb</td> <td>2</td> <td>18</td> <td>£848</td> <td>£30,528</td> </tr> <tr> <td>Mar</td> <td>1</td> <td>18</td> <td>£848</td> <td>£15,264</td> </tr> <tr> <td colspan="4">Total</td> <td>£320,544</td> </tr> </tbody> </table>		Months	Patients	Cost per month	Cost	Oct	6	18	£848	£91,584	Nov	5	18	£848	£76,320	Dec	4	18	£848	£61,056	Jan	3	18	£848	£45,792	Feb	2	18	£848	£30,528	Mar	1	18	£848	£15,264	Total				£320,544
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5.4	<p>Recurrent overall costs per annum <i>(including additional costs)</i></p> <p>The recurrent costs of implementing this therapy will be included in the HSC Board financial planning assumptions for predicted growth in this area from 2015/16.</p>																																								

5.5	<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 dimethyl fumarate.</p>
6	<p>Expected implementation period</p> <p>This therapy is currently available in Northern Ireland on a cost per case basis. It is expected that this therapy will be formally commissioned during the final quarter 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 the drug costs. For patients being considered for drug treatment for RRMS, it is expected that dimethyl fumarate be considered as an option for treatment alongside the currently available disease modifying therapies (DMTs).</p>
7	<p>Commissioning arrangements</p> <p>This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially 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 BHSCCT and the final profile of resources and monitoring arrangements agreed.</p>
8	<p>Monitoring arrangements</p> <p>The extant monthly monitoring return will be amended to capture the number of patients receiving treatment with this regime. This is reviewed monthly by the Specialist Service Commissioning Team.</p> <p>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.</p>
9	<p>DHSSPS 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>