

NICE TA 303 – Teriflunomide for treating relapsing-remitting multiple sclerosis

1	<p>Summary of NICE TA 303</p> <p>Teriflunomide is recommended 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 teriflunomide with the discount agreed in the patient access scheme. <p>Teriflunomide would be considered for people with active RRMS as an option, in the same way as glatiramer acetate and the beta interferons, and would be used in line with the Association for British Neurologists' guidelines, and would be stopped if the person's condition converted to secondary progressive multiple sclerosis, or reached Expanded Disability Status Scale (EDSS) state 7.</p>										
2	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>Each year in Northern Ireland the number of patients with MS accessing disease-modifying therapies (DMTs) increases by around 100. Discussion with clinicians has indicated that around 20% of new patients are likely to commence on teriflunomide.</p> <p>The costing template for NICE TA303 indicates that up to 50% of people currently on first-line DMTs may switch to teriflunomide. At the end of March 2014, there were 1,328 patients in NI on first-line DMTs. MS clinicians have indicated that discussions would be required with patients about transferring to teriflunomide to confirm clinical suitability but anticipate that during 2014/15 around 10% of patients currently on first-line DMTs will transfer to teriflunomide.</p> <p>There is also a group of patients (clinical estimate of 25 – 30 patients) who are eligible for first-line DMTs in NI but who are not currently on treatment because of a reluctance to use injectable treatments. It is projected that the majority of this cohort are likely to take up the option of treatment with teriflunomide.</p> <p>During 2014/15, it is therefore projected that approximately 180 patients will commence treatment with teriflunomide. Table 1 below summarises the projected position in 2014/15.</p> <p>Table 1</p> <table border="1"> <thead> <tr> <th>Patient Category</th> <th>Projected Numbers 2014/15</th> </tr> </thead> <tbody> <tr> <td>New patients commencing on DMTs accessing teriflunomide</td> <td>20</td> </tr> <tr> <td>Existing patients on first-line DMTs transferring to teriflunomide</td> <td>135</td> </tr> <tr> <td>Patients eligible for first-line DMTs not currently on treatment commencing on teriflunomide</td> <td>25</td> </tr> <tr> <td>Total projected patient numbers in 2014/15</td> <td>180</td> </tr> </tbody> </table>	Patient Category	Projected Numbers 2014/15	New patients commencing on DMTs accessing teriflunomide	20	Existing patients on first-line DMTs transferring to teriflunomide	135	Patients eligible for first-line DMTs not currently on treatment commencing on teriflunomide	25	Total projected patient numbers in 2014/15	180
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3	Costs
3.1	<p>Cost per patient per annum</p> <p>The manufacturer has stated that the list price of teriflunomide is £1037.84 per 28-tablet pack (excluding VAT). Based on the list price, the manufacturer has estimated the annual cost of teriflunomide to be £13,529 per patient per year.</p> <p>However, the manufacturer of teriflunomide has agreed a patient access scheme with the Department of Health. This is a simple discount scheme, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
3.2	<p>In year cost per patient per annum (for new and prevalent cases)</p> <p>The estimated additional in year cost based on the pre PAS cost of £13,529 per patient per year is £0.564m.</p>
3.3	<p>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 first-line DMTs for those patients already on treatment will offset the total requirements of introducing teriflunomide.</p>
3.4	<p>Recurrent overall cost</p> <p>The estimated additional recurrent cost based on the pre PAS cost of £13,529 per patient per year is £1.128m.</p>
4	<p>Expected implementation period</p> <p>It is expected that this therapy will be available for use in NI during the first quarter of 2014/15. This introduction will be subject confirmation of the level of funding available and submission of an IPT by Belfast Trust. For new patients being considered for drug treatment for RRMS, it is expected that teriflunomide be considered as an option for treatment alongside the currently available DMTs.</p> <p>For patients currently on first-line DMTs, the switch to teriflunomide, if clinically appropriate, will be discussed as patients come to clinic for review.</p>
5	<p>Commissioning arrangements</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>
6	<p>Monitoring arrangements</p> <p>The extant monitoring system will be amended to capture patient commencement, suspension and cessation on this regime. This is reviewed monthly by the Specialist</p>

	<p>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>
7	<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>