

NICE TA 254: Fingolimod for the treatment of highly active relapsing - remitting multiple sclerosis

1	<p>Name of Commissioning Team</p> <p>Specialist Services Commissioning Team</p>
2	<p>Summary of NICE TA 254 – Fingolimod for the treatment of highly active relapsing-remitting multiple sclerosis</p> <p>Fingolimod is recommended as an option for the treatment of highly active relapsing–remitting multiple sclerosis (MS) in adults, only if:</p> <ul style="list-style-type: none"> • they have an unchanged or increased relapse rate or ongoing severe relapses compared with the previous year despite treatment with beta interferon, and • the manufacturer provides fingolimod with the discount agreed as part of the patient access scheme (PAS) The amount of the PAS is commercial in confidence.
3	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>Under the NICE costing template the expected uptake for fingolimod would be 17 new patients per annum.</p> <p>Northern Ireland has higher incidence and prevalence rate of MS and patients tend to have higher compliance with treatment regimes. In light of this advice has been sought from the local specialists providing the service and it has been agreed that an uptake of around 30 new patients per annum is a more reasonable planning assumption.</p>
4	<p>Outcomes</p>
4.1	<p>Additional life expectancy gain / progress improvement</p> <p>MS is a chronic, disabling, neurological condition that is life altering and has a substantial negative impact on quality of life and activities of daily living.</p> <p>Fingolimod is a valuable new therapy and its <u>oral</u> formulation represents innovation in the treatment of eligible patients with MS because currently available treatments are administered by injection.</p> <p>Fingolimod is licensed as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups:</p> <ul style="list-style-type: none"> • patients with high disease activity despite treatment with a beta-interferon, or • patients with rapidly evolving severe relapsing remitting multiple sclerosis

	<u>NICE TA 254 only recommends use of fingolimod for the first of these patient groups</u>
4.2	Reduction in morbidity Studies show that when compared to placebo, patients taking fingolimod had fewer relapses per year and were at lower risk of disability progression. When compared to interferon beta-1a injections, patients taking fingolimod had fewer relapses per year. There was no difference between fingolimod and interferon beta-1a in the time to disability progression.
4.3	Cost per patient per annum Fingolimod is given as one 500 microgram capsule once daily. According to the most recent BNF (BNF63, March 2012), a pack of 28 capsules costs £1,470.00. Therefore the annual drug cost per patient is £19,162.50 Patients eligible for Fingolimod under NICE TA 254 will already be receiving beta interferon treatment which will cease when they commence treatment on the new regime. Cost per patient for fingolimod will therefore be net of the costs of their current treatment. The current weighted average cost for existing treatment per annum per patient are estimated as £8,400 (BNF costs). The additional cost per patient will therefore be £10,763, per annum. A patient access scheme is also available for fingolimod. HSCB is assured that Belfast Trust will avail of this scheme.
4.4	In year cost per patient per annum (for new and prevalent cases) It is estimated that 15 patients will start on Fingolimod in this financial year. Using the cost per patient figure of £10,763, it is estimated that in year costs for these 15 patients will around £81,000.
4.5	Any cost savings and how these will be secured Patients being prescribed fingolimod will no longer require beta interferon injections. On average the annual cost of beta interferon is £8,400. (The weighted BNF cost of all drugs currently in use at March 2012) The cost of introducing fingolimod will be offset by reduced prescribing of beta interferon. Using a rate of £8,400 for 30 patients the savings will amount to a total of £252,000 per annum.
4.6	Recurrent overall cost The total recurrent overall cost will be £323,000 for 30 patients per annum. The Belfast Trust will further be expected to avail of the patient access scheme for fingolimod.

4.7	<p>Cost per QALY</p> <p>NICE concluded that the most plausible ICER for fingolimod compared with the comparators was likely to be in the range of £25,000 to £35,000 per QALY gained. NICE recognised that including all of the benefits of fingolimod which may not be adequately captured in the QALY calculation could decrease the ICER to a level that would be considered a cost-effective use of NHS resources.</p>
4.8	<p>Other treatments available for this condition (highly active relapsing–remitting multiple sclerosis (MS) in adults</p> <p>Beta-interferons (Avonex[®], Betaferon[®], Extavia[®], Rebif[®]) Glatiramer acetate (Copaxone[®])</p>
4.9	<p>Readiness to implement</p> <p>Implementation of this NICE TA (254) requires that eligible patients will need to be switched from beta interferon. The regime involves a move from administration by injection to an oral therapy. It also requires initial assessment and ongoing cardiac monitoring. Arrangements should be developed where clinically appropriate to do so, to offer patients access to cardiac monitoring in their local Trust.</p>
5	<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>
6	<p>What will Commissioning do to secure funding for the implementation of this TA including any proposals for disinvestment</p> <p>Resources from the 2012/13 and 2013/14 specialist drugs allocations will be used to support this regime. Funds provided will be net of the cost of existing regimes available to eligible patients. The Belfast Trust will also avail of the patient access scheme.</p>
7	<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. An investment proposal template will be completed by the BHSCT and the final profile of resources and monitoring arrangements agreed.</p>
8	<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>

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.

The Trust will, within 6 months provide written confirmation of protocols agreed to allow patients to avail of clinical monitoring closer to home where clinically appropriate to do so.