Multiple Sclerosis Society

MS Society response to the NICE Appraisal consultation document (ACD) Teriflunomide for treating relapsing remitting multiple sclerosis October 2013

About the MS Society

Established in 1953 and with over 38,000 members and more than 300 branches, the MS Society is the UK's largest charity for people affected by multiple sclerosis (MS) and the largest not-for-profit funder of MS research in Europe. There are approximately 100,000 people with MS in the UK and, with 50 new people diagnosed every week, it is one of the most common neurological conditions affecting adults. We are committed to bringing high quality standards of health and social care within reach of everyone affected by MS.

Introduction

The MS Society welcomes the opportunity to respond to the ACD for teriflunomide in treating relapsing remitting multiple sclerosis. We include the views of people with MS as well as those of a number of expert medical advisors specialising in MS.

We are very disappointed that the Committee's draft recommendation reports that there is insufficient evidence to support teriflunomide as a cost effective medicine to be made available in the NHS. We urge NICE to reconsider its decision on teriflunomide for the treatment of relapsing remitting multiple sclerosis for the following reasons:

1. Potential to significantly enhance quality of life, which, as accepted by the Committee, was not fully captured in the QALY
2. Clinical effectiveness in reducing relapse rates compared to a placebo, as recognised by the Committee in the ACD
3. Innovative benefit of teriflunomide in offering a first-line oral (and therefore convenient) treatment option with a favourable adverse effects profile
4. Wider benefits of teriflunomide including enabling a person to live with less requirement for care and support and the potential to remain in work
5. Cost effectiveness based on the relative pricing of other first-line treatments

Further details on our reasons are provided here and we also refer NICE to our previous submission on the single technology appraisal of teriflunomide.

1. Evidence from people with MS

The Committee highlighted that, as an oral treatment, teriflunomide offered a step change for treating people with relapsing remitting multiple sclerosis which could have a substantial impact on quality of life. The MS Society strongly agrees with this opinion; and shares the Committee's view that the quality of life benefits of an oral treatment were not fully captured in the QALY. For this reason we ask the appraisal committee to take into full consideration and appropriately weight the views and experiences of people with MS.

People with MS fear the residual disability a relapse may cause, which can vary from mild to severe, and which is unpredictable in nature. In our survey of more than 1000 people with relapsing remitting MS, 78 per cent said that they always or often worry about how their relapse impacts on those around them; 95 per cent were unable to maintain activities during a relapse and 90 per cent considered that relapses result in a lack of independence[1]. The patient representative giving oral evidence to the Committee stressed that once on teriflunomide, she was able to stay employed and take part in family life.

NICE must give due weight to the physical and emotional impact of relapses and not underestimate the potential for this treatment to significantly enhance quality of life.

2. The proven efficacy of teriflunomide

The MS Society agrees with the conclusion of the Committee that 'teriflunomide was clinically effective in reducing relapse rates compared with placebo, and that it may have a beneficial impact on accumulation of disability' (4.4, page 34).

The worrying, painful and distressing nature of a relapse and the loss of independence, are all a fundamental concern for people with MS, having a great impact on quality of life. The evidence shows that patients being treated with teriflunomide experienced 30 per cent reduction in the number of relapses, which is similar to current first-line therapies.

There is a clear professional consensus that treating people early with the most effective treatment is essential to preserve people's quality of life. Removing the option of any one effective treatment would be to condemn some people unnecessarily to a life governed by debilitating relapses and the accumulation of disability.

The MS Society is concerned that an assumption of waning of treatment effect has been included in the ACD, without any evidence being provided to substantiate such an assumption or the reduced efficacy that the Committee perceives. We would like to know the evidence behind this conclusion, particularly in respect of the assumption that there will be a 50% decrease in treatment effect after 5 years.

---

[1] Heinonen R, Brown D, Holloway E. *Perspectives of people with MS on relapses and disease modifying drugs.* MS Society, 2010.

3. The value of innovation

The Committee deemed teriflunomide to be an innovative technology, a view with which the MS Society would wholly agree, given the markedly different method of administration compared to current first-line injectable MS therapies.

As the Kennedy report recommended, innovation should be considered and appropriately weighted as part of the decision making process. Teriflunomide meets many of the health-related benefits criteria listed by Kennedy[2] including:

- the ability to offer a different mode of administering a drug – in this case, a tablet rather than an injection or infusion for first-line treatment;
- the opportunity to be treated at home rather than attend a hospital or clinic;
- improvement in quality of life including enjoyment of greater dignity and independence – this treatment will give people with MS and their carers greater freedom;
- the ability to minimise the social visibility of disease or care – a tablet can be taken more discretely and is less disruptive than infusions or injections.

It is not clear from the ACD to what extent the above factors have formally been taken into account by the committee, or how each may have been weighted in the decision making process.

Over 95% of 1000 people with MS said that a pill would be their treatment method of choice[3]. The patient satisfaction data referred to in the ACD also shows a greater preference for teriflunomide when compared to Rebif-44: 'At week 48 the global satisfaction score was statistically significantly higher with teriflunomide than Rebif-44 (higher score indicates better satisfaction; 68.818 compared with 60.975, p=0.0162)' (3.5, page 9).

NICE should note that the clear preference for a pill as a preferred treatment method is based on the following factors:

- added convenience and therefore enhanced quality of life
- physical and psychological barriers to injecting
- freedom from injection site reactions
- ease of administration and less dependence on a friend, family member or carer

The Committee heard from the patient representative who gave evidence that using injectable treatments had been a 'dark part' of her life, including being ill for 2 days after the injection and worrying for the following 5 days about the next injection.

Enhancing quality of life for people with MS and their carers should be a fundamental concern for NICE. We therefore strongly encourage NICE to consider the evidence

[2] Kennedy I. *Appraising the value of innovation and other benefits: a short study for NICE. 2009.*
[3] Heinonen R, Brown D, Holloway E. *Perspectives of people with MS on relapses and disease modifying drugs.* MS Society, 2010.

provided by people with MS regarding their preference for an oral treatment option, particularly as teriflunomide would provide the first oral option as a first-line therapy.

Additionally, the inconvenience of a treatment is compounded by the additional healthcare costs due to extra appointments required to help manage side effects and help with problems related to injections.

4. Wider benefits of treatment

The ACD accepts that quality of life benefits of an oral treatment were not fully captured in the QALY, but there are additional wider benefits to which we feel that NICE should give more consideration.

As the Kennedy report[4] stated, the wider benefits that should be taken into account include:

- ability to join the workforce
- staying in work and reducing absenteeism
- independence for carers
- reduction in social costs
- increased tax revenue

Symptoms of MS, including the emotional and physical impact of MS relapses, have a significant effect on people's ability to care for families and to carry out paid employment. The restriction of this ability during a relapse is of great concern and importance to people with MS. Research has shown that 37 per cent of people in paid employment take more than two weeks off work during a relapse[5].

This evidence is backed up by the Work Foundation Report which found that on average 37 per cent of people with 'mild' MS are working and many more have had to change or quit their jobs due to the fluctuating nature of their MS[6]. It also reported that 44 per cent of people with MS retire early, in comparison with the 35 per cent European average, and up to 80 per cent of people with MS retire within 15 years of diagnosis, severely shortening the working lives of young adults[7].

Teriflunomide offers the potential for many people to continue working and to contribute to society. Current first-line options, either injections or infusions, can severely restrict people in what they can do, and force affected individuals to reduce their working hours or stop employment altogether.

Enabling a person to live more independently, experience fewer relapses and require less care and support would improve their lives as well as their carers'. The Work Foundation report found that 'Professional careers of 57 per cent of relatives are

---

[4] Kennedy I. *Appraising the value of innovation and other benefits: a short study for NICE.* 2009.
[5] Data from Zajicek JP, Ingram WM, Vickery J, Creanor S, Wright DE, Hobart JC. Patient-orientated longitudinal study of multiple sclerosis in south west England (The South West Impact of Multiple Sclerosis Project, SWIMS) 1: protocol and baseline characteristics of cohort. BMC Neurol. 2010 Oct 7;10:88. PubMed PMID:20929556; PubMed Central PMCID: PMC2966453
[6] Bevan S, Zheltoukhova K, McGee R, Blazey L. *Ready to Work? Meeting the Employment and Career Aspirations of People with Multiple Sclerosis.* London: Work Foundation, 2011.
[7] ibid

adversely affected by MS of a family member'[8]. The MS Society believes that a wider view must be taken when assessing the cost and benefits of teriflunomide.

5. Cost-effectiveness

We believe teriflunomide should be considered a cost-effective treatment for the following reasons:

- We understand a Patient Access Scheme (PAS) has been agreed. Given discounts elsewhere, it seems reasonable to assume that the PAS is likely to bring the cost of teriflunomide in line with those medicines considered part of the MS Risk Sharing Scheme (RSS).
- Compared with Copaxone, Avonex, Rebif and Betaferon, teriflunomide not only has similar (slightly better) efficacy, but all the benefits of oral delivery, making it the treatment of choice for many people with MS. As recognised by NICE, 'teriflunomide dominated the blended comparator in the base case… it was less expensive and more effective' (3.16, page 16).

Given teriflunomide's potential to improve health outcomes without placing a greater burden on the tax payer or the NHS, we believe it would be perverse not to provide this medicine on the NHS.

Final comments

While the MS Society believes that there is sufficient evidence for the Committee to recommend the use of teriflunomide, we urge the manufacturer to meet NICE's requests for further clarification and analyses in time for the second Appraisal Committee meeting.

If the Committee accepts that teriflunomide is at least as effective as current options, given the benefits to patients, the innovative nature of the treatment and its cost effectiveness would logically lead the appraisal to reach a positive outcome for people with MS.

If you would like any further information about the points raised in this submission, please contact [redacted], [redacted] – [redacted] or [redacted].

[8] Bevan S, Zheltoukhova K, McGee R, Blazey L. *Ready to Work? Meeting the Employment and Career Aspirations of People with Multiple Sclerosis.* London: Work Foundation, 2011.