Multiple Sclerosis Society

MS Society response to the NICE Appraisal consultation document (ACD) Alemtuzumab for treating relapsing remitting multiple sclerosis January 2014

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 more than 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 alemtuzumab 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 alemtuzumab as a cost effective medicine to be made available in the NHS. We urge NICE to reconsider its decision on alemtuzumab for the treatment of relapsing remitting multiple sclerosis for the following reasons:

1. Potential to significantly enhance quality of life
2. Clinical effectiveness in reducing relapse rates and a beneficial impact on sustained accumulation of disability at 6 months compared with subcutaneous interferon beta-1a
3. Innovative benefits of alemtuzumab
4. Wider benefits of alemtuzumab including enabling a person to live with less requirement for care and support and the potential to remain in work
5. Evidence of cost effectiveness

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

1. Evidence from people with MS

The Committee highlighted that alemtuzumab offers a step change for treating people with relapsing remitting multiple sclerosis, with evidence from clinical specialists stating that it has been a revolutionary treatment for some people, allowing them to live their lives as they had before they were diagnosed with MS (4.14). The MS Society strongly agrees with this opinion. 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 expert giving oral evidence to the Committee stressed that once on alemtuzumab she had not experienced any relapses, with her health being better now than at the time of diagnosis with MS and the considerable impact on her family lessened (4.3).

As the Committee states, while alemtuzumab is associated with some risk of serious adverse effects some people with MS are willing to accept this risk because of the treatment's significant benefits (4.7). In light of the Committees' recognition of these benefits, 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 alemtuzumab

The MS Society agrees with the conclusion of the Committee that 'alemtuzumab was a clinically effective treatment in reducing relapse rates and had a beneficial impact on sustained accumulation of disability at 6 months compared with subcutaneous interferon beta-1a in people with relapsing remitting MS' (4.8). Phase III trials showed alemtuzumab to have a greater clinical effect on reducing relapse rates than any of the current first-line therapies.

The MS Society agrees with the clinical specialists that alemtuzumab should be used as a first line option instead of other disease modifying therapies, as well as where other treatments have not been effective and preferably earlier rather than later (4.3). The clinicians pointed out that this would include those who had been on natalizumab and for whom no other treatments are currently recommended. Given this advice and the proven efficacy of alemtuzumab the MS Society sincerely hopes that the Committee will change its current view not to recommend alemtuzumab for rapidly evolving severe and highly active relapsing remitting MS.

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

There is a clear professional consensus that treating people with MS early with the most effective treatment is essential to preserve people's quality of life and as stated in the ACD, 'any delay in relapse and progression of disability … would have a positive impact on the lives of people with MS' (4.2). Removing the option of any one effective treatment would be to reduce the possibility that people find a treatment that works for them (in efficacy and tolerance levels) and condemn some people unnecessarily to a life governed by debilitating relapses and the accumulation of disability as well as an increased reliance on health and social care services.

3. The value of innovation

As the Committee is aware, current first line treatments for relapsing remitting MS are administered by injections weekly or several times a week or monthly infusions, while alemtuzumab is an annual intravenous infusion taking 5 consecutive days in the first year and 3 consecutive days 12 months later (some people requiring further infusions in later years). The Committee concluded that a reduction in the frequency of treatment would have a positive impact on the lives of people with MS and their families (4.2) and that alemtuzumab provides a step change in the treatment of relapsing remitting MS (4.14), views with which the MS Society would wholly agree.

In addition, alemtuzumab has been shown to reduce the risk of sustained accumulation of disability and also provides the first MS treatment option that does not have to be discontinued for a person to have children (4.7).

As the Kennedy report recommended, innovation should be considered and appropriately weighted as part of the decision making process. Alemtuzumab 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, an annual infusion rather than an injection or monthly infusion for first-line treatment;
- 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 – an annual infusion is less disruptive than injections required daily or several times a week, or a monthly infusion.

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.

In our survey, the responses indicated a preference for a therapy that would easily fit in a person's everyday life and normal activities, without debilitating side effects, enabling them to stay in paid employment and to be able to care for their family

[2] Kennedy I. *Appraising the value of innovation and other benefits: a short study for NICE. 2009.*

rather than being cared for[3]. The Committee heard from the patient expert who gave evidence that alemtuzumab's administration schedule was preferable to weekly or daily self-administered injections with beta interferons, which to her would have been a constant reminder of her MS (4.3). The patient expert also explained that she had been given enough information during the initial stages of treatment to help her understand that monitoring would be essential to prevent adverse events (4.7).

4. Wider benefits of treatment

The ACD concludes that alemtuzumab has the potential to benefit people with relapsing remitting MS and their families (4.3) and that relapsing remitting MS can have a substantial negative impact on quality of life and activities of daily living (4.2). The clinicians told the Committee that the potential benefits of alemtuzumab to quality of life are 'considerable' (4.7). However, there are additional wider benefits of alemtuzumab to which we feel strongly 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 and wellbeing for carers
- reduction in social care and welfare 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 in the UK 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].

Alemtuzumab offers the potential for many people to continue working and to contribute to society. The current first-line options administered by injection can

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

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 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 alemtuzumab.

5. Cost-effectiveness

We strongly believe that the evidence supports alemtuzumab as a cost-effective treatment, including the following conclusions from the Evidence Review Group (ERG):

- The ERG's own preferred base case approach resulted in alemtuzumab dominating subcutaneous interferon beta-1a (3.28).
- All of the ERG's sensitivity analyses showed that alemtuzumab was a cost effective treatment.
- The ERG carried out exploratory analyses for the subgroup with highly active relapsing remitting MS despite interferon use, and the subgroup with rapidly evolving severe relapsing remitting MS, and showed that 'alemtuzumab continued to dominate fingolimod and natalizumab' (3.31).

Given the potential of alemtuzumab 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 alemtuzumab, we urge the manufacturer to meet NICE's requests for further clarification and analyses in time for the second Appraisal Committee meeting on 21 January 2014.

The available evidence has merited alemtuzumab to be licensed in the EU. The MS Society stresses that it should be made available in line with this licence, without any restrictions for certain populations of people with relapsing remitting MS.

If the Committee accepts that alemtuzumab dominates other current options, and given the benefits to patients and the innovative nature of the treatment, this 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], MS Society – [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.