NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Teriflunomide for treating relapsing forms of multiple sclerosis

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation:

Are you (tick all that apply):

X a patient with the condition for which NICE is considering this technology

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. **Advantages**
(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Relapses
Since starting teriflunomide I have not suffered a relapse. My life is near enough back to normal and because I have not suffered a relapse my health is better. I think my health will remain on an even keel for the long term if I am able to continue to use this technology. The reduction in relapses has not only been beneficial to me but also to my whole family. They don't need to visit me as often or bring me my shopping. I think they worry about me less because they can see my health has improved. My general fitness has also improved. I'm walking faster and I am able to do more physical things, like gardening.

My relapses were quite severe and disabling. During a relapse I was unable to do the most basic things like house work, cooking, cleaning, washing, ironing and generally looking after my family. I would be wiped out all day unable to move and function. I always tried to go to work until I was unable to cope there.

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Administration of teriflunomide and convenience
The administration of teriflunomide is the best way so far to administer MS medication. Taking a tablet once a day has enabled me to have a better quality of life as I am not stressed about having to administer an injection. The house had constant reminders of my illness in several rooms including the fridge, kitchen and utility room. Now the pack sits on the table and it looks like any other box of pills. I take the box wherever I go and I don't need a doctor's note to fly with them. This means I'm less stressed when leaving the house, as I don't have to pack lots of paraphernalia. The convenience of a once a day pill by far outweighs the injectables - no more waiting for drugs to be delivered and bins collected.

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

Course and/or outcome of the condition
I now consider myself as healthy as the next person; people who have not seen me for a year or so can't believe how well I look. I still suffer from "down days" when I'm fatigued and just need to rest. It happens when I try to do too much or ignore my body when it needs to stop, I think I should be able to carry on as I used to and can get quite upset with myself with the dawning realisation that I can't. People try to tell me it's because I'm getting older, but I think they're wrong. I used to feel down on the days before my injection was due. I would get agitated and withdrawn from my family. These days are less frequent now as I don't need to worry about injecting myself anymore and I feel that I'm in charge of my MS. Overall I'm in good health and as healthy as some of my work colleagues. I'm hoping to start hill walking again in the near future as I feel I'm ready to get back up the mountains. Before teriflunomide I wouldn't even entertain the idea.

Physical symptoms
My physical symptoms have lessened and those I have are minimal and manageable. They are mainly sensory symptoms like tingles on my forehead, elbow, buttock and chin. They only last a few hours so they don't impact on my life.

Pre teriflunomide some of my symptoms were around so frequently like the electric shock down the spine I used to miss it when it wasn't there. I used to say hello to the tingles in my legs and ask them where they'd been. Eric the spider used to visit every day running amok under the skin on my head. He only makes an appearance when

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I'm tired at the end of the week these days. My symptoms became very personal to me as I saw them as a part of me and in a way became protective of them.

Pain
The pain I was experiencing as a result of my MS has lessened and is now more of an irritation than a problem and can now be managed through my GP. At first I didn't know what this itching (the only way to describe it) all over my legs was. It was so bad that the only way to get some relief was to scrub my legs with a scrubbing brush. This left me bleeding and bruised, when eventually I saw my neurologist he diagnosed me with neuropathic pain and prescribed mild antidepressants to manage the pain.

Level of Disability
I don't consider myself to suffer any disability at all. I may have been numb from the waist down but still manage to walk. Disability to me means I am unable to carry on living a normal life and that I don't fully recover from a relapse.

Mental health and well-being
Before the treatment I was always drained and mentally tired. Every day was an up-hill struggle and I was sometimes low and depressed. Every day merged into one. Outwardly I was the life and soul of the party, inwardly I was struggling.
When I suffered relapses I would get very emotional and down. I was constantly blaming myself for the way I was feeling. I felt I needed to fight with myself all the time, as I was always trying to carry on as normal. I thought that was the only way to get better. I don't think about my MS very often now because there is no need to worry about it. I'm feeling very positive about the future and I am looking forward to doing some of the things I used to do. Now I'm full of life. I have a positive outlook since starting the trial because I'm feeling physically better and mentally stronger.

Quality of life
This technology has already changed my life. I am now able to make plans for the short term future as I don't worry about the next relapse waiting around the corner. I feel positive about the future because of this treatment. Before there was always an uncertainty about what the future would hold. Before my diagnosis I was a very active person. I had 4 jobs at one time as well as running a house and taking care of my family. As a family we would go to Snowdonia at the weekends and walk the mountains. We all had roller skates and played roller hockey with friends. We had a caravan and I took up sea fishing and this meant climbing down cliffs to get to the best spot. I was always decorating and cleaning my house from top to bottom every week. I never stopped. I think that is why I am determined not to be beaten by this disease. When I was diagnosed everything stopped especially when I started the treatments. I became frightened in case I fell over, slipped or had a brain shake. Even though none of this happened I thought that it was a strong possibility.

As a result of taking teriflunomide I am able to manage all my housework myself, decorate; clean the windows, manage the garden and other slightly strenuous jobs. Now I'm ready to start it all again. I have already walked up to the Rosydd slate

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quarry in Snowdonia and next I may try Tryfan. It might take me a little longer this time but I'm ready to try. I'm going to the Isle of White in September for a week of fossil hunting, then onto Somerset for another week of fossil hunting.

My quality of life has improved since I have been taking this medication I no longer worry about going out with my family in case the evening has to be cut short, and I can now plan days out. My family worry about me less than previously as they can see the improvement and I need less personal care.

Help staying in work
I am able to continue working with minimal absenteeism which helps my employers and colleagues and also keeps me physically active and my mind busy.

Positive impact on carers
My MS is not just mine it affects the rest of my family. Previously my family have had to plan and organise days out or even going out for a meal in case I'm too tired. My mum worried all the time and she put herself under great stress by doing so. I tried to minimise the impact on my family but I also tried to be as honest as possible. My husband takes on most of my care and it has been very hard for him. He works all over the country and has in the past had to ask his employer to try and give him local jobs. They have been very understanding and since starting the terifluomide he has been able to work all over the country, as I do not need as much care. Since starting teriflunomide I don't need his assistance as frequently, only when I'm fatigued. My son is 22 and I try to never ask him for help because he has his own life to lead and I'm sure he doesn't want to see his mum struggling, as I wouldn't mine.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. **Disadvantages**
Please list any problems with or concerns you have about the technology.
Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

There are no disadvantages as far as I'm concerned with this treatment. I have not suffered any side effects and the care I have received has been excellent.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

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N/A

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

N/A

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

I am aware of the following existing treatments for MS: Avonex, Rebif, Betaferon, Extavia, Copaxone, Tysabri and Gilenya.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

I have tried the following treatments and each had their own specific problems:

Copaxone - Daily
When I was administering the Copaxone daily I was not too worried about injecting because it was subcutaneous. It was uncomfortable but I didn't suffer any other side effects until I had been injecting for about 6 months. My skin became painful around the injection sites, itching, hot, bruised and lumpy flesh which looked like it was sinking. After one particularly bad injection in my stomach the needle injected the fluid under my skin causing a massive lump, which was full of blood. At that point I decided enough was enough, so I contact my nurse and she suggested Avonex.

Avonex - Weekly
I thought administering Avonex would be better because it was only once a week. I was warned that it could make you feel quite ill but I decided to give it a go. How bad could it be? I started injecting in my thigh muscles once a week and from the onset I felt terrible. I would have to mentally prepare myself for administering Avonex, which I did religiously on a Tuesday at 10pm. I warmed the vial and prepared my painkillers - 2 for after the injection and 2 for beside the bed, for when I woke in the

night feeling like I'd been hit by a train. No one was allowed in the front room after 9.30pm as I needed to psych myself up to fire that needle into my leg. On one particular night my son forgot and walked into the room just as I was about to press the button. As I saw him I completely lost the plot, screaming and shouting that he knows to leave me alone as I do this every week at the same time and he'd just ruined it and I'd have to start again! I completely overreacted but trying to push that button takes a lot of effort when you know how bad you will feel in the morning. After waking in the night to take more pain killers I would try and get back to sleep but often I would be writhing round the bed in pain. I was aching all over. I had a headache, felt lethargic and generally unwell which led to my poor husband not getting much sleep either. After getting up for work I would arrive groggy, my shoulders slumped carrying a pack of painkillers. I was a supervisor at the time and my staff knew that on a Wednesday not to speak to me until at least lunch time. They'd just make me a cup of chocolate and leave it on my desk. I was administering about 50 solpadeine a month just to function**.** After a period of time I suffered 3 disabling relapses in a row, after discussions with my nurse I decided to try Rebif.

Rebif – 3 times a week

I administered Rebif 3 times a week. At first I thought it would be better because the dose was spread out over the week, whereas Avonex was just one large dose. From the offset I had skin reactions and aches and pains in the middle of the night but not as bad as before.

Decision Time

I decided to withdraw all treatments after returning from my brother's wedding in Santorini. I spent the whole of the week feeling terrible because of the side effects of Rebif. I looked terrible in the wedding pictures not only because I was feeling so unwell but I had big red patches on my arms where I'd been injecting. On the flight home I felt cheated that I had spent most of my holiday feeling so unwell and had in a way missed enjoying my brother's special day. I decided then and there that I would withdraw from all treatments. I might suffer a relapse every 12 months which might last a couple of days or weeks, or I could feel unwell for most of the time when taking these medications. The choice was easy. As soon as I got home I called my MS nurse and said I wanted to stop all treatments and take my chances. She knew I had tried the various treatments available to me and respected my decision.

I noticed after I stopped taking Rebif my moods changed and it was like a cloud had been lifted from over me. My manager called me into her office and said she'd seen a change in my manner. I told her I had stopped my medication and was feeling better. After stopping Rebif I realised that not only did it make me feel bad it seemed to change my personality, I was very unsettled, introvert and moody.

Teriflunomide has the following advantages of the current treatments:

No side-effects

I have suffered no side effects while I have been taking this new technology.

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Overall condition
I feel that my condition has approved overall, I feel and look better and my mind seems clearer. I've not suffered a relapse since I started the TOWER study and my symptoms have lessened. I occasionally might get a tingle on my face or around my left elbow but they never last. I think the MS sometimes likes to remind me that it's still there but I know who's in charge.

Reduction in relapses
I have not suffered a relapse since I started on the treatment. I only suffer from minor complaints that do not affect my day to day life. Mostly I get random tingles around my body. It could be spiders running round in circles on my skull, tingles on my elbow, tingles on my forehead or chin and some neuropathic pain around my body. None of these symptoms impact on my life compared to the relapses I have suffered previously. Previously I have suffered a brain stem relapse and I was unable to get up without vomiting and suffered from double vision. On another occasion I woke up one morning having no feeling from the waist down. I tried to be as normal as possible and went to work but eventually I had to take a couple of weeks off and have a course of steroids from the doctor.

Easy to administer
The medication is so easy to administer compared to the injectables and I don't have to prepare to go out for the day. I can just slip the box into my bag and I don't have to worry about cold packs, other paraphernalia and trying to find a suitable place to inject that's hygienic. Taking teriflunomide has made me feel like I don't have MS. Sometimes I forget I have it because I feel my life is as it should be, normal. I don't think I need as much help as before from my family because I have now got more confidence and know my limitations. It's so easy to stick to taking the treatment because I am in a routine now; it's just like taking a tablet for a headache or a daily vitamin pill. It's now become part of my day.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

I don't think that this technology has any disadvantages. My experience has only been positive - no relapses and very minor complaints. The technology is so easy to use compared to other technologies it fits in your hand bag and best of all no side effects for me personally.

Equality and Diversity

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NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- Could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- Could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- Could lead to recommendations that have any adverse impact on people with a particular disability or disabilities

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts

N/A

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

N/A

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

N/A

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

N/A

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

There would not be the constant reminder around the house that you have MS. You would be able to look in the fridge and not see medication, look on the side and not see a sharps bin. You wouldn't have to carry your injector pen, cool pack, sharps bin on a day out. This in turn means that the worry you feel post injection is non-existent. Taking this little pill once a day makes the biggest change to your life that only

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someone who injects on a regular basis would understand. It can help a person with MS to regain a sense of freedom and normality. Carers too would benefit from teriflunomide as the patient's health improves they would be able to do more for themselves. This in turn would alleviate some of the stress placed on carers and they also would regain some sort of control of their own lives.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

If the technology wasn't made available on the NHS I personally wouldn't return to injecting. Life before teriflunomide was bleak and dark. Thinking back to that time fills me with dread. I don't think I would have been able to stay in work much longer had I not been offered this chance. My employers were worried about not only my health but also my state of mind. Trying to live a normal life whilst suffering the side effects caused by the injectables made my life unbearable. It even upsets me to think about those times. I also know it upset my family to see me so unwell. If this technology was not made available to patients it would be a great shame. This technology has changed my life, without this opportunity my life would be so different. This technology has given me hope, control and my dignity back. I feel other people including carers would benefit from this technology. Sufferers could see an improvement in their condition and would not need to rely on carers as frequently.

Are there groups of patients that have difficulties using the technology?

N/A

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

None