

Tuesday, 11 June 2013

PBAC Secretariat
MDP 952
Department of Health and Ageing
GPO Box 9848
Canberra ACT 2601

To whom it may concern,

Re: Dimethyl Fumarate (Tecfidera) – July 10-12, 2013 PBAC Agenda.

MS Australia is writing to support the inclusion of the relapsing remitting MS treatment, Dimethyl Fumarate (**Tecfidera**) on the Pharmaceutical Benefits Scheme (PBS).

As the national peak body for people with MS in Australia we are proud to advocate on behalf of our member organisations for the MS community. One area in particular that we are passionate about is the provision of more affordable and accessible treatments that can improve the lives of people with MS.

There are currently 23,000 people living with MS across the country with an additional 1000 diagnoses every year. MS can be a particularly debilitating disease with an unpredictable disease course that affects people in different ways. For some people, it is a disease of differing severity with periods of unpredictable relapse and remission. For others it is a progressive decline over time. For all, it is life changing.

As such, MS Australia supports any treatment that helps to minimise the impact of the disease and allow people with MS to live more fulfilling lives.

There are currently six treatment options for people with relapsing remitting MS, the most commonly diagnosed form of the disease. These treatments include four injectable medications, a monthly IV infusion and one oral medication. Whilst these treatments have all played a part in improving the lives of people with MS in Australia they are not without their drawbacks.

The injectable medications reduce the rate of relapse in people with MS by approximately 30% however they can also cause considerable side-effects such as injection site reactions, pain, flu-like symptoms, palpitations, anxiety and depression. Delivering a self-injecting treatment is also an onerous task that can cause undue stress on a person with MS. This stress is compounded if the person suffers from needle phobia or their disability is such that they can't administer the treatment themselves. The responsibility, or burden, to administer treatment in this instance falls to their carer who can be a health professional or a loved one.

An infusion treatment performed monthly, has been shown to reduce the rate of relapse for people with MS however it poses a risk of a potentially fatal side effect, progressive multifocal leukoencephalopathy (PML), which means patients receiving this treatment are required to do so in hospital day procedure centres and undergo increased medical monitoring and supervision.

Oral medications definitely alleviate a lot of the stress related to taking MS medications. The only oral medication available was listed on the PBS in 2011. It too requires six hour cardiac monitoring at commencement, together with ongoing monitoring with blood tests due to the risk of possible liver impairment and infections.

However this particular oral treatment is not suitable for every person with MS. Therefore MS Australia would support the addition of another oral medication to the market rather than an injectable or more infusion treatments.

Tecfidera has been shown in clinical trials to reduce relapse rates and slow the rate of disability progression in people with relapsing remitting MS. It is not yet available to people with MS in Australia as it is listed for consideration by the TGA but if approved, the cost of a private prescription would be too much for many people with MS. This would mean people who could benefit from the treatment miss out. Listing the treatment on the PBS is the only way to make the treatment affordable and accessible to the 23,000 Australians living with MS.

As we have already outlined, the challenges faced by people with MS can be significant and can have a devastating impact on families, and the wider community. Relapses can result in short-term or long-term disability, resulting in the need for physical and psychological care and support, medical investigations, treatments and hospitalisation.

These symptoms or the gradual progression of the disease through relapses mean that the majority of people with MS are unable to work. In fact people with MS are more likely to be unemployed than those with any other chronic disease.

This contributes to an increasing economic burden of MS on the rest of society. Currently, the economic cost of MS to the Australian community is estimated to be around \$1.04 billion a year. This is an increase of \$380 million since 2005.

Being able to better manage and limit the impact of relapses helps give people with MS greater certainty to get on with their lives, and disease modifying treatments like Dimethyl Fumarate help them to maintain important parts of their lifestyle for longer, such as employment, physical activity and exercise, as well as travel and socialising with friends.

Whilst these elements may not seem particularly significant, together, they give a person with MS purpose, focus, independence and drive which can be very useful in maintaining a high quality of life and staying on top of their symptoms.

More broadly, it can also mean less time in hospital, meaning less strain on valuable medical and disability resources, a lower cost for at home modifications and support and prolonged employment, which helps to reduce the economic impact of MS on society.

Tecfidera is not without side-effects. Evidence from clinical trials suggests that it can cause diarrhoea, cramps, liver function test (LFT) elevation, nausea and flushes.

However, pending a positive assessment of efficacy and safety from the Therapeutic Goods Administration, this medication will make a valuable addition to the repertoire of medications available to people with MS and their neurologists. It will allow for an appropriate treatment choice to be made according to the efficacy and possible side-effects in relation to an individual's circumstances and will help to alleviate the economic cost of MS to individuals, their families and the broader community.

We appreciate you considering this treatment for inclusion on the PBS.

Regards,



Debra Cerasa
Chief Executive Officer
Multiple Sclerosis Australia