

Wednesday, 24th September 2014



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

To whom it may concern,

Re: PLEGRIDY™ November PBAC Agenda

MS Australia is writing to support the inclusion of the relapsing remitting MS treatment PLEGRIDY™ on the Pharmaceutical Benefits Scheme (PBS). As the national peak body for people with MS we are proud to advocate on behalf of our member organisations and the MS community. One area we are particularly passionate about is the provision of more affordable and accessible treatments that can improve the lives of people with MS.

There are currently more than 23,000 people living with MS across the country with an additional 1000 diagnosed every year. MS can be a particularly debilitating disease with an unpredictable disease course. No two cases of MS are the same. There is no one-size fits all treatment for people living with MS and to date, there is no known cure.

The challenges faced by people with MS can be significant and can have a devastating impact on their families and the wider community. Relapses can result in short term or long term disability, resulting in the need for physical and / or 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 retain their employment . 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 frequency and impact of relapses can help alleviate the burden of MS on the community and the individual.

During clinical trials, Plegridy has been shown to have comparable effectiveness to the currently available interferon beta-1a agents, helping to reduce the annualised relapse rate compared to placebo by approximately 36% for those treated every two weeks. Additional data from the trial also suggested a significant reduction in brain lesion load as visible by magnetic resonance imaging, with the two-weekly injections again showing a larger effect.

Importantly, Plegridy is a sub-cutaneous injectable therapy meaning it can be easily used and will alleviate some of the stress associated with the intra-muscular injections of Avonex. The fact Plegridy is pegylated to extend its half-life will also allow for less frequent dosing, in some cases at least halving the dosage schedule of comparable treatments such as Avonex.

Plegridy is not without potential side effects. As with the weekly injections of interferon beta-1a, the most common side effects demonstrated in clinical trials were injection site reactions, flu-like

symptoms, fever and headache, though these are less frequent given the dosing schedule. More rare, serious adverse events included blood disorders and kidney disorders. These side effects are of comparable severity and incidence to the currently available interferon beta-1a therapy.

Overall, MS Australia believes Plegridy provides another valuable treatment option that will help to reduce the burden for many people with MS and its potential effectiveness at reducing relapse rates and severity could allow people with MS to maintain 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 provide 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 ultimately mean less time in hospital, reducing the drain 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.

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,

A handwritten signature in black ink, appearing to be 'Debra Cerasa', enclosed within a large, loopy oval shape.

Debra Cerasa

Chief Executive Officer

Multiple Sclerosis Australia