

Tuesday, 11 February 2014

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

To whom it may concern,

Re: FAMPYRA® (Fampridine) – March 2014 PBAC Agenda

MS Australia is writing to support the inclusion of the oral medication FAMPYRA® (Fampridine) to 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 state member organisations and people affected by the disease. 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 has been deemed safe by the Therapeutic Goods Administration (TGA) that helps to minimise the impact of the disease and allows people with MS to live more fulfilling lives.

There are currently a number of treatment options for people with relapsing remitting MS, the most commonly diagnosed form of the disease. These treatments include injectable medications, a monthly IV infusion and oral medications. All of these medications attempt to address the progression of MS in patients, lessening the frequency and severity of relapses and attacks - a common characteristic of the disease.

FAMPYRA is one treatment on the market that addresses a common symptom of MS – mobility impairment – rather than disease progression. It is estimated approximately

MS Australia
Level 26 Northpoint Building,
100 Miller St
NORTH SYDNEY NSW 2060
T: 02 9468 8390
F: 02 9411 7456

half of people diagnosed with MS will suffer mobility impairment within 15 years of diagnosis and a recently published study showed that 43% of people with MS considered walking impairment to be their most debilitating symptom.¹

Mobility impairment in MS can lead to muscle weakness, poor nerve conduction and spasticity in muscles. There are also associated risks of falls and fractures, increased fatigue caused by increased energy expenditure, psychological distress, discrimination, social isolation, access barriers, transport difficulties, loss of employment, economic hardship and increased dependence on carers. Combined with disease progression, this can have a major influence on a person with MS and their ability to complete basic daily activities, most importantly employment. In fact one of the primary reasons people with MS cite for leaving the workforce are issues associated with mobility impairment.

People with MS being unable to work places an increasing economic burden on the rest of society. Currently, the economic cost of MS to the Australian community is estimated to be more than \$1 billion a year. This is an increase of \$380 million since 2005. It is also estimated that 50% of the total cost of MS on the economy is due to lost productivity for people with MS and their carers.²

However, if people with MS are able to better manage symptoms through proven treatments it will help to give them greater certainty to get on with their lives, and 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 condition. 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.

Therefore, focusing on improved and effective treatment will be cost effective, not only in terms of dollars, but improved productivity, quality of life, independence, reduced social isolation and depression.

FAMPYRA is the first drug that improves walking speed in some people with MS. In Phase III clinical trials FAMPYRA improved walking speed by 25% in approximately 35% of MS patients. There are no treatments currently available under the Pharmaceutical Benefits Scheme (PBS) to improve walking speed caused by MS.³

¹ Pike J et al., Social and economic burden of walking and mobility problems in multiple sclerosis. BMC Neurol. 2012;12:94.

² Covance, Palmer A. Economic impact of multiple sclerosis in 2010 Report. Prepared for MS Research Australia by Covance Pty Ltd, North Ryde, NSW and Prof Andrew Palmer, Menzies Research Institute Tasmania, TAS, Australia: 2011.

³ Goodman AD et al., Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. Lancet. 2009;373(9665):732-8

Furthermore as a symptom modifying therapy, FAMPYRA is effective regardless of disease course and can be prescribed in conjunction with other medications. It is also the only treatment currently available that offers some relief to people with progressive forms of the disease.

FAMPYRA is prescribed in a monthly dose with every third month provided free of charge by the manufacturer. Currently a monthly course of the treatment costs \$595, and the total annual cost exceeds \$5,300. This is not a viable long-term solution for the provision of the product as it is too expensive for many people with MS and their families. As a result, people who could benefit from the treatment are either missing out or having to source generic versions of the product from compounding pharmacists.

It is important to note FAMPYRA is not without its own particular side effects. During clinical trials some of the adverse effects included nausea, headaches, dizziness, constipation, anxiety and back pain. There is also a risk of seizures. However the treatment has been deemed safe and effective by the TGA and MS Australia believes it will make a valuable addition to the repertoire of medications available to people with MS and their neurologists.

MS is a complex disease and there is no 'one size fits all treatment'. Therefore it is important to have a number of treatment options available to give people with MS and their neurologists, freedom and flexibility to find the best treatment options. Effective treatments that address debilitating symptoms like mobility impairment such as FAMPYRA will also help to alleviate the economic cost of MS to individuals, their families and the broader community.

We appreciate you considering new MS treatments for inclusion on the PBS.

Regards,

A handwritten signature in black ink, appearing to be 'Debra Cerasa', written over a circular stamp or seal.

Debra Cerasa
Chief Executive Officer
Multiple Sclerosis Australia