Multiple Sclerosis Research Australia
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Re: COPAXONE 20 and 40® (glatiramer acetate) for Clinically Isolated Syndrome – July 2017 PBAC Agenda

MS Research Australia is writing to support the inclusion of the medications Copaxone 20 and 40® (glatiramer acetate) to the Pharmaceutical Benefits Scheme (PBS) for people with Clinically Isolated Syndrome.

As the largest organisation dedicated to funding and coordinating MS research in Australia, we are proud to advocate on behalf of people affected by multiple sclerosis, and its precursor Clinically Isolated Syndrome (CIS). Decades of research have led to significant improvements in our understanding of MS, and how it can be best be treated and managed. It is of particular importance to MS Research Australia that this research is translated and implemented into the availability of affordable and effective treatments that can reduce the impact of MS for individuals and the Australian community as a whole. As such MS Research Australia supports the affordable availability of all efficacious and safe treatment options that have been show in clinical trials to benefit people with MS and related disorders.

People who have been diagnosed with clinically isolated syndrome (CIS) are at high risk of developing multiple sclerosis (MS). However, there are no medications that have been approved for PBS reimbursement leaving people with this condition and their doctors to take a 'wait and see' approach to manage the condition. This leaves patients in a situation of heightened uncertainty and increased risk of experiencing a second damaging clinical or radiological event.

The inclusion of Copaxone 20 and 40® on the PBS register, would represent the first affordable and evidence-based treatment available to people with CIS.

During the PreCISe clinical trial, evidence emerged that taking Copaxone was significantly effective at reducing the conversion of people with CIS to MS compared to placebo, leading to the study being amended to compare receiving Copaxone early after a CIS diagnosis vs delaying the treatment. Copaxone significantly reduced the risk of developing MS by 45% and the time to conversion was prolonged by 115% compared to placebo[8]. In addition to the health and wellbeing benefits that this affords individuals, this represents a source for multiple financial benefits to the economy and health sector. People with MS lose more days to illness and use more disability services than the general public. They are also more likely to retire from work early and reduce the number of hours they work. Delaying conversion to MS after a diagnosis of CIS would partially alleviate these costs.

In recent years, evidence has accumulated that now enables clinicians to more readily identify people with clinically isolated syndrome who are at the highest risk of converting to clinically definite MS[1]. In Addition, the benefits of early vs delayed treatment, including the long-term benefits on disability outcomes, have also been clearly demonstrated in a large number of studies for people with CIS[2-12].

MS Research Australia welcomes the prospect of an affordable treatment option for people with CIS that has undergone rigorous clinical testing. This will provide the opportunity for people with CIS and their doctors to commence an effective therapy to reduce the risk of further

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relapses and delay a diagnosis of MS. This in turn will provide increased certainty and security for these patients and those around them – their family members and carers.
MS Research Australia appreciates the opportunity to make this submission, and applauds the Committee for seeking the views of patients and the wider community as part of the process of considering new MS treatments for inclusion on the PBS.

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