

Online submission to PBAC regarding Copaxone® for Clinically Isolated Syndrome

Submissions to be lodged by 7 June at:

https://www.health.gov.au/internet/main/publishing.nsf/Content/PBAC_online_submission_form

Medicine: Copaxone® (glatiramer acetate)

Date of PBAC register: July 2017

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Declaration of interest:

MS Australia is making this submission as we have an interest in the health and well-being of all people with multiple sclerosis (MS). MS Australia is the national peak body for people living with MS in Australia. We work with governments at all levels, engaging on the issues that concern the lives of people living with MS, their families and carers, the community and the economy. We declare that we have received funding support from Teva Pharma Australia Pty Ltd and from other pharmaceutical companies with an interest in MS in the form of grants for advocacy activities.

Consumer input:

MS Australia is writing to support the inclusion of the medication glatiramer acetate (marketing name Copaxone®) for people with Clinically Isolated Syndrome to 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 and its precursor, Clinically Isolated Syndrome (CIS).

CIS refers to a first episode of inflammatory demyelination in the central nervous system that could become MS if additional activity occurs.

There are currently more than 23,000 people living with MS across the country. 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. The economic cost of MS to the Australian community has been estimated to be around \$1.04 billion a year.

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.

The research indicates that 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.

In addition to the health and wellbeing benefits that this affords individuals, this represents a source for overall 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.

Research indicates that in recent years, evidence has accumulated that now enables clinicians to more readily identify people with CIS who are at the highest risk of converting to clinically definite MS. 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.

MSA 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 relapses and delay a diagnosis of MS. This in turn will provide increased certainty and security for these patients and their family members and carers.

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

How did you learn about this consumer submission process?

From PBAC web-site.

SUBMIT (BUTTON)