

## **On-line submission to March 2022 meeting of PBAC**

### **Glatiramer acetate (Copaxone®) in the form of a pre-filled pen.**

#### **1. Please outline your experience with the medical/health condition**

MS Australia is writing to the Pharmaceutical Benefits Advisory Committee (PBAC) to support the inclusion of a new listing for glatiramer acetate (Copaxone®) in the form of an injection containing glatiramer acetate 40mg in 1 mL single dose pre-filled pen on the Pharmaceutical Benefits Scheme (PBS) for people with multiple sclerosis (MS). This listing would be under the same conditions as the PBS-listed glatiramer acetate pre-filled syringe.

MS Australia is Australia's national MS not-for-profit organisation that empowers researchers to identify ways to treat, prevent and cure MS, seeks sustained and systemic policy change via advocacy, and acts as the champion for Australia's community of people affected by MS. MS Australia is the largest Australian not-for-profit organisation dedicated to funding, coordinating, educating and advocating for MS research as part of the worldwide effort to solve MS. MS Australia collaborates closely with our member organisations and various national and international bodies to help meet the needs of people affected by MS.

#### **2. How is the medical/health condition currently treated?**

There are some 15 disease-modifying therapies (DMTs) currently on the PBS, including glatiramer acetate (Copaxone® and Glatira®).

Currently, more than 25,600 people living with MS across the country and over 7.6 million Australians know or have a loved one with this potentially debilitating disease. MS can be particularly debilitating and has 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.

Including an "easier to use" form of this medication on the PBS 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, their dexterity and ability to self-administer medication and will help to alleviate the economic cost of MS to individuals, their families and the broader community.

According to a recent DUSC Report, 1,675 patients were treated with glatiramer acetate in 2020. Whilst, over time, the number of people with MS treated with injectable DMTs such as glatiramer acetate is decreasing in comparison to treatment by infusion or oral medicines, they remain an important part of the range of DMTs available to suit the needs of individuals.

### **3. What do you see as the advantages of this proposed medicine, in particular for those with the medical condition and/or family and carers?**

MS Australia has been advised that the glatiramer acetate (Copaxone®) pen has been launched in a number of countries including Israel and Germany.

**Considering the extensive range of available medications to treat MS in Australia, it is still critical to ensure that current medications are as up to date as possible in terms of patient comfort and considers all available strategies to promote long term drug adherence and persistence.**

Previous research using pre-filled pens for self-injection with other MS medications has demonstrated their effectiveness in relieving injection anxiety, which is a major contributor to promoting adherence to treatment (Phillips et al). Additionally, being able to successfully self-administer injections assists in building self-efficacy and self-management in people with MS. A study focusing on self-efficacy in patients using Copaxone® has shown that higher self-efficacy scores led to greater adherence to the medication (Fraser et al), which is a major goal of enacting a treatment management plan in chronic illness.

MS Australia is aware of other studies in chronic illness that show that improving ease of injection helps adherence. Lessons learnt by improvements in the way insulin can be self-administered by people with diabetes is a good example.<sup>1</sup> The conclusion of a 2019 study by Gandell et al, stated that “Adherence to prescribed therapy is key to clinical outcomes, and the effect is particularly critical for treatments that require regular injections. Potential barriers to maintaining adherence with an injection regimen were generally similar from the perspectives of HCPs and women of childbearing age, with needle size and needle visibility, fear/anxiety, and perceptions of pain among the major concerns identified.”

Further this study concluded that “The use of an autoinjector is additionally perceived by HCPs to be easier and safer to use, and is likely to further reduce the barriers to medication acceptance and adherence among women of childbearing age who require a regimen of regularly scheduled injections.”

People with MS often experience sensory and/or motor disturbances to their limbs as part of the demyelination process to the central nervous system. This can have more obvious impacts in terms of ambulation and walking, but there can be more subtle issues with finger, hand and arm movements. For people with MS prescribed Copaxone, there has been reasonable access to devices that assist with self-injection of the drug, and these have been an important part of self-management and adherence to the medication. However, for people with MS experiencing issues with finger, hand and arm dexterity, the available measures to assist self-injection may still not be enough to ensure safe, accurate and complete self-injection delivery. The current two approved injection systems of pre-filled syringe and syringe inserted into an autoinjector, still require certain fine motor skills to

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<sup>1</sup> [https://www.pharmacytimes.com/view/r566\\_12oct\\_diabetes](https://www.pharmacytimes.com/view/r566_12oct_diabetes)

accomplish the task successfully. However, this may be outside the scope of ability for some people after an acute MS relapse, or due to residual disability from previous MS relapses.

Additionally, MS Australia believes that there is a definite clinical need for glatiramer acetate (Copaxone®) regarding pregnancy planning. Although there are other oral and infusible options available, some injectable therapies are key at certain times in the life of a person living with MS. This is particularly relevant in the preconception and active conception phases where many other approved drugs may be contraindicated. In fact, many other DMTs are not approved for use during pregnancy and are recommended to be ceased. This could lead to long-term effects on the central nervous system if pregnancy takes time to be achieved (Sandberg-Wollheim et al). It has been deemed reasonable to conclude that for patients who are taking glatiramer acetate it may not always be necessary to stop therapy while attempting to become pregnant. Furthermore, among women who, in the opinion of their neurologist, require DMT coverage during pregnancy, glatiramer acetate therapy may be considered (Sandberg-Wollheim et al).

**Having a comfortable and easy injection option available is crucial to maintaining MS stability during this time of change for these patients.**

Finding the right treatment option for every individual with MS is paramount as suboptimal treatment can lead to an increased symptom burden and irreversible accumulation of disability. This in turn leads to an increased burden on the healthcare system and a further reduction in the quality of life of patients and their families.

For the reasons outlined above regarding ease of use, increased adherence, and suitability of use during pregnancy, and the flow-on benefits that will occur, MS Australia believes that the introduction of the glatiramer acetate (Copaxone®) pen will be of considerable benefit to those in the MS community utilising this particular DMT.

**What do you see as the main disadvantages of this proposed medicine?**

Perhaps the only disadvantage we can see would be learning to use a new device for self injection, but only for some patients. However, MS Australia has been advised by the sponsor that their Patient Support Program, Care Xone is available to support patients throughout the duration of their Copaxone therapy, i.e. the pre-filled syringe and the pen, once available in the market. Patients are provided with a welcome kit, CSYNC device and other educational resources and they will be offered access to the sponsor's Patient Portal.

**4. Please provide any additional comments you would like the PBAC to consider**

Feedback directly from patients using Copaxone®

When the PBAC agenda was published in December 2021, MS Australia posted about the proposal for the listing of the glatiramer acetate (Copaxone®) pen on the PBS on its social

media channels. Here are some examples of the kinds of feedback we received from the MS community:

“the pre-filled Pen would be so much easier, sounds like a very good idea.”

“A pre-filled pen sounds good in theory. I have used 2 versions of the auto injector for Copaxone. It was very stiff & hard to manipulate. Never designed for those with decreased fine motor hand issues. Caused lots of problems with bleeding, bruising and infected injection sites because you had to push down hard to get it to work. This was several years ago. So, yes to a pre-filled pen but with great design for those with hand issues.”

“I suffer excruciating pain and red welts each time I inject. Happy if I don’t have to go through that anymore.”

“I struggle finding a spot to inject on my tummy and I don’t want to do it in other places as I have permanent lumps and bumps from this on one leg above my knee from when I did move to a different place.”

## References

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Gandell DL, Bienen EJ, Gudeman J. Mode of injection and treatment adherence: results of a survey characterizing the perspectives of health care providers and US women 18-45 years old. *Patient Prefer Adherence*. 2019;13:351-361. Published 2019 Feb 22.

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