Online submission to PBAC regarding siponimod (Mayzent®) for Secondary Progressive MS (SPMS)

Submissions to be lodged by 12 February at:
https://www.health.gov.au/internet/main/publishing.nsf/Content/PBAC_online_submission_form

Medicine: **siponimod (Mayzent®)**

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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 in the past received funding support from Novartis and from other pharmaceutical companies with an interest in MS in the form of grants for projects.

Consumer input:

MS Australia is writing to support the inclusion of the medication siponimod (brand name Mayzent®) to the Pharmaceutical Benefits Scheme (PBS) for people with secondary progressive MS (SPMS). 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 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.

Secondary progressive MS (SPMS) occurs following an initial relapsing-remitting course (RRMS). Some people who are diagnosed with RRMS will eventually transition to a secondary progressive course in which there is a slow and gradually progressive worsening of neurologic function (accumulation of disability) over time, usually independent of relapses. SPMS can be further characterised at different points in time as either active (with relapses and/or evidence of new MRI activity) or non-active, as well as with or without ongoing progression (evidence of continued disease worsening over time).

In March 2019 the U.S. Food and Drug Administration approved siponimod (Mayzent®) for the treatment of adults with clinically isolated syndrome, (an initial neurological episode) and relapsing forms of MS, including those with active SPMS.

In a large clinical trial of 1,651 people with SPMS, fewer people taking siponimod (Mayzent®) had confirmed worsening of disability progression compared to those on placebo. It also decreased the number of relapses.

The approval of siponimod was welcomed by the National MS Society in the U.S. as an important breakthrough for people with SPMS, a new treatment option for people with active SPMS and the hope that approval will stimulate development of more treatments for progressive MS.

The challenges faced by people with MS can be significant and can have a devastating impact on their families and the wider community. Relapses, as part of the course of either RRMS or SPMS, 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.

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.

The published results of the Phase III clinical trial of siponimod, known as EXPAND, showed that siponimod was able to reduce the risk of progression in people with SPMS. The authors said, "For patients with SPMS, even numerically small changes in expanded disability status scale (EDSS) score can correspond to substantial changes in neurological function and daily activities".

Including this medication on the PBS will make a valuable addition to the repertoire of medications available to people with MS, especially those with SPMS, 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.

Our colleagues at MS Research Australia will be making a submission that includes detailed research information regarding siponimod (Mayzent®).

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)