Online submission to PBAC regarding ozanimod (Zeposia®) for Relapsing Remitting MS (RRMS)

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

Medicine: **ozanimod (Zeposia®)**

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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 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 ozanimod (brand name Zeposia®) to the Pharmaceutical Benefits Scheme (PBS) for people with relapsing remitting MS (RRMS). 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 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.

The relapsing-remitting (RRMS) form of MS is characterised by partial or total recovery after attacks, also called exacerbations, relapses, or flares. It is the most common form of MS with 70 to 75% of people with MS initially diagnosed with a relapsing-remitting course.

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 RRMS 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.

Ozanimod belongs to the same class of drugs as Gilenya (fingolimod).

It acts on certain types of white blood cells (lymphocytes) which are involved in the autoimmune attack on myelin seen in MS. It binds to special locations (or receptors) on the surface of the lymphocytes, called sphingosine-1-phosphate receptors (S1P-R). This causes a larger proportion of lymphocytes to be retained in the lymph glands. The number of activated lymphocytes reaching the brain is decreased, resulting in reduced immune attack on nerve cells in the brain and spinal cord.

Phase III clinical trials for ozanimod (called SUNBEAM and RADIANCE) compared ozanimod to interferon beta 1a (Avonex). Overall the trial results showed a reduction in the annual relapse rate, a significantly reduced number of new active lesions seen on MRI, and reduced brain volume loss compared to Avonex.

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

Like fingolimod (Gilenya), ozanimod is an oral medication and as such, will bring the many well-known benefits of an oral treatment compared to injectable and infusion MS treatments such as: improved compliance with dosage, ease of storage, ease of administration (we've been told many times "let's face it, most people don't want to stick a needles in themselves"), reduced burden of monitoring and removing the burden of spending time in hospital.

In addition, unlike fingolimod (Gilenya), treatment with ozanimod does not involve the need for observation for six hours to monitor heart rate. This will be of particular interest and benefit to those newly diagnosed with RRMS.

Being able to better manage and limit the frequency and impact of relapses, reduce the number of new lesions and reduce brain volume loss, can help alleviate the burden of MS on the community and the individual.

The Health Economic Impact of MS in Australia study reported that MS is estimated to have cost the Australian community $1.75 billion in 2017 with an average cost of MS per person of $68,382 (similar to that of someone with Parkinson's disease or the first year after a stroke, triple that of a person with type 2 diabetes).

Including 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 additional 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.

An application for a licence to market ozanimod as a treatment for relapsing remitting MS has been submitted to the European Medicines Agency (March 2019) with a decision expected in the first half of 2020.

The National Institute for Health and Care Excellence in the UK (NICE) has begun an appraisal of ozanimod for RRMS to decide whether it should be prescribed by the NHS in England and Wales. Scotland and Northern Ireland will carry out separate appraisals.

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)