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Online submission to PBAC regarding ocrelizumab (Ocrevus®) for Primary Progressive MS (PPMS)

Submissions to be lodged by 10 June 2020 at:

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

Medicine: Ocrevus® (ocrelizumab)

Date of PBAC register: July 2020

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Declaration of interest:

MS Australia is supporting this re-submission as we have an interest in the health and well-being of all people with 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 Roche in the past, and from other pharmaceutical companies with an interest in MS, in the form of grants for advocacy activities and other projects.

Consumer input:

MS Australia is writing to support the inclusion of the medication ocrelizumab (marketing name Ocrevus®) to the Pharmaceutical Benefits Scheme (PBS) for people with primary progressive MS (PPMS). 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 most intensely so for those with the primary progressive form of MS who, to date, have no treatments available.

There are currently approximately 25,600 people living with MS across the country. MS can be a particularly debilitating disease, especially for those diagnosed with the progressive forms of MS. The challenges faced by people with MS can be significant and can have a devastating impact on their families and the wider community. The progressive forms of MS inevitably lead to long term disability, resulting in the need for physical and/or psychological care and support, medical investigations, treatments and hospitalisation.

These symptoms associated with PPMS and the gradual progression of the disease, mean that the majority of people with PPMS are unable to retain their employment. In fact, people with MS are generally 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 \$1.75 billion a year.

As stated in more detail in the submission provided by MS Research Australia, which we commend to you, the economic costs of MS significantly increase as disability increases. As reported in the "Health Economic Impact of MS in Australia in 2017", the costs of MS increase with increasing disability severity. The costs more than tripled in people with severe disability (\$114,813) compared to those with no disability (\$30,561) (https://msra.org.au/wp-content/uploads/2018/08/health-economic-impact-of-ms-in-australia-in-2017_ms-research-australia_web.pdf). This is also reflected

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in the value of NDIS plans. Early indications of the value of NDIS plans for people with MS average around \$60,000 per year, with the value of plans rising to well over \$150,000 per year as the severity of disability increases. Therefore, a treatment that can delay the progression of disability can have a significant economic benefit.

Ocrelizumab is a monoclonal antibody that reduces the numbers of B cells in the immune system, thought to be involved in the inflammatory attacks that cause MS relapses. The first dose is given as two intravenous infusions, two weeks apart, and each subsequent dose is given six monthly thereafter.

In clinical trials, ocrelizumab was shown to slow the continued progression in disability (a reduction in the relative risk of disability progression of 25%). People taking ocrelizumab had fewer active lesions, fewer new lesions and lower overall brain volume loss, compared to placebo.

More information regarding clinical trial data, the efficacy of ocrelizumab and its side effects is included in the submission from MS Research Australia, referred to earlier.

As with all MS medications, the efficacy, side-effects and tolerability of a drug can vary greatly between individuals, and it is for this reason that a range of affordable treatment options is necessary to increase the chance of every individual finding an effective and well tolerated treatment that suits their individual circumstances. Even a modest delay in disability can provide enormous benefit to an individual, their families and the broader community and ocrelizumab provides the first “ray of hope” to those with PPMS who have not had the benefit of any treatment options in the past.

Since ocrelizumab for PPMS was not recommended when first submitted to the PBAC in late 2017, and most recently, following the re-submission of ocrelizumab to the PBAC by the sponsor, MS Australia has encouraged those affected by PPMS to make submissions to PBAC via our social media channels. We trust this will result in the PBAC receiving helpful submissions from the PPMS community.

Sammy’s story (Sammy is 27 and was diagnosed with PPMS in 2013):

“Speaking with others who are living with MS, I’ve found that a common frustration is the uncertainty that surrounds the illness. It is as difficult to anticipate symptoms as it is to treat them. Primary progressive MS specifically is significant in this regard as there are no official medications and all treatment programs address symptoms rather than the condition itself.

Despite being diagnosed in 2013, the condition continues to surprise me each day. I often wake up feeling stiff and foggy; sometimes too exhausted to leave my bed at all. I struggle with long walks, climbing stairs and balance in general. It is difficult to perform basic tasks and commit to long-term activities. My online study allows flexibility to manage my own schedule but I do occasionally experience cognitive impairment and fatigue, impacting both study and my personal life. The journey so far has improved my resilience and allowed me to embrace and understand uncertainty on a very palpable level. I am completing a Masters in Cultural Leadership with NIDA and my experiences provide a unique perspective to apply to the course.

The introduction of a medication specifically designed for PPMS will remarkably improve my quality of life. I look forward to a day where I can walk comfortably, stand without having to build myself up and make plans without being plagued by doubt. People with MS have an insight and perspective

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that would be invaluable were we given the opportunity to contribute more to society on a tangible level.”

Matt’s story (Matt is in his mid 40s):

“The hardest thing about my PPMS is that it changes so quickly. For me that has meant dramatic and rapid changes to my mobility since I was diagnosed. 3 years ago I was very physically active, running more than 60km a month, playing soccer an hour or two a week. Today, I rely totally on my powerchair to get around and to continue working. With the speed of progression, no one knows what exactly my mobility will allow me to do at the end of this year, indeed even the end of this month.

Keeping up with how quickly things change means constantly adapting to new challenges and limitations, on a monthly and even weekly basis. With support from MS Australia, my employer and co-workers have been amazing at helping me in making constant adaptations. My family is my biggest support, with major impacts on every aspect of how we live.

It is entirely due to all this continual support and adaptation that I am still in full-time work today. I am a senior academic and manager at an Australian university, head of a department of more than 40 staff. But I simply don't know how long this adaptation can continue. Being in my mid 40s, if I were able to stop the disease progression today, I would expect with the adaptations already in place to be able to continue working for the next 20 or 30 years. Even slowing the progression might allow me to work out to retirement age and would reduce the huge pressures on my family and support network in making those constant adaptations. Otherwise, I have learned from experience only to make plans for the coming 2-3 month window; I simply don't know what will happen beyond then.

Professor Matt Duckham”

Robin’s story (Robin was diagnosed with PPMS in 2004):

“I am one of the 10 per cent of the 25,600 people in Australia with Primary Progressive Multiple Sclerosis.

My diagnosis of MS in 2004 of Relapsing Remitting MS was changed to PPMS four years later. At this time, unlike the nearly dozen drugs available for RRMS, there was none for PPMS. That is no suitable treatment for me and roughly 2300 people (a very conservative estimate).

In those few years after diagnosis my MS progressed rapidly. Initially I used one standard walking stick, changed to an elbow crutch then two crutches and now a walker 100pc of the time. That is just one of the visible signs of MS. Probably the more debilitating symptoms are those that people don't see – the cognitive decline, the pain, the decreased motor skills and the fatigue.

Due to many of the above symptoms I accepted a redundancy offer in late 2012 and quit my job as a journalist. A few weeks later I started a trial for a drug called ocrelizumab, recommended to me by my neurologist as the ONLY option he had.

I would like to say ocrelizumab has changed my life, but it hasn't. It has, however, slowed down my progression to the extent that my neuro believes that had I not been on the trial I would now more than likely be in a wheelchair.

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The ocrelizumab trial covered about 760 people around the world and showed a slowdown in progression of nearly 25 per cent. That is significant and allows people renewed hope, a chance to continue employment, have social inclusion and enjoy family life.

Now that is approved by the TGA, unless it is listed on the PBS it will be out of reach financially for me and several thousand people.”

Overall, MS Australia believes ocrelizumab provides the first viable treatment option for people with PPMS that will help to reduce the burden for many people with MS and its potential effectiveness at reducing the progress of MS could allow people with MS to maintain parts of their lifestyle for longer, such as employment, physical activity and exercise, as well as travel and socialising with friends.

Whilst these elements may not seem particularly significant, together they provide a person with MS purpose, focus, independence and drive which can be very useful in maintaining a high quality of life and staying on top of their symptoms. More broadly, it can ultimately mean less time in hospital, reducing the drain on valuable medical and disability resources, a lower cost for at home modifications and support, and prolonged employment, which helps to reduce the economic impact of MS on society.

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)