



10 February 2021

PBAC Secretariat
MDP 952
Department of Health and Ageing
GPO Box 9848
Canberra ACT 2601

By email to: pbac@health.gov.au

Re: Submission of ofatumumab (Kesimpta®) for RRMS to PBAC meeting March 2021

MS Australia is writing to the Pharmaceutical Benefits Advisory Committee (PBAC) to support the inclusion of ofatumumab on the Pharmaceutical Benefits Scheme (PBS) for people with multiple sclerosis (MS).

- MS Australia is the national voice for people with MS. MS Australia works in advocacy and communications and collaborates with its stakeholders to benefit thousands of people affected by MS across the country.
- The Research Division of MS Australia is the largest national not-for-profit organisation dedicated to funding MS discoveries and coordinating MS research in Australia.

Declaration of interest

MS Australia is making this 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 in the past received funding support from pharmaceutical companies, including Novartis Pharmaceuticals Australia Pty Ltd, with an interest in MS in the form of grants for projects and support of our national MS Research scientific conference.

About MS

As the national peak body for people with MS we are proud to advocate on behalf of our state 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.

MS affects everyone differently and people also respond to treatments and their potential side effects differently. Life circumstances, such as family planning, career and travel, as well as other

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health conditions, can also greatly affect treatment options and decisions. Even geography can affect treatment choices with close access to hospitals and health professionals for treatment, administration and monitoring being a big consideration relating to some medications for people with MS living outside of major metropolitan areas. There is no one-size fits all treatment for people living with MS and to date, there is no known cure.

The relapsing-remitting form of MS (RRMS) 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 cause short term or long term disability, resulting in the need for physical and/or psychological care and support, medical investigations, treatments and hospitalisation.

About ofatumumab (Kesimpta®)

Ofatumumab is a monoclonal antibody against CD20, a molecule found on a subset of B cells, and acts as a B cell-depleting agent. B cells are involved in the pathophysiology of MS, and monoclonal antibodies against CD20, rituximab (Rituxan) and ocrelizumab (Ocrevus), have been shown to be effective disease-modifying therapies for MS¹. Ofatumumab is the only fully human antibody molecule of the three and binds a distinct region of the CD20 molecule to rituximab and ocrelizumab².

The American Food and Drug Administration (FDA) has approved the use of ofatumumab for the treatment of relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting MS (RRMS), and active secondary progressive MS (SPMS)³. This treatment has been used since 2009 for the treatment of chronic lymphocytic leukemia (under the tradename Arzerra), but has been restricted in some markets.

Clinical trials

In the Phase III clinical trials named ASCLEPIOS I and II, ofatumumab was compared against teriflunomide (Aubagio). Across the two trials 946 patients were randomly assigned to receive ofatumumab and 936 to receive teriflunomide. ASCLEPIOS I showed that annualised rates of MS relapses was 0.11 per year for patients who received ofatumumab, compared to 0.22 per year for teriflunomide. In ASCLEPIOS II, the rates were 0.1 per year for ofatumumab versus 0.25 per year for teriflunomide. Ofatumumab-treated patients also experienced less worsening of disability than people treated with the comparison drug, as well as dramatically lower numbers of lesions on MRI (eg 97% reduction in gadolinium enhancing lesions per T1-weighted MRI scan compared to the comparator; $p < 0.001$). While there were no significant effects on brain volume, ofatumumab-treated patients exhibited lower levels of a biomarker of neurodegeneration in the blood (serum neurofilament light).

Ofatumumab was well-tolerated in both studies. Adverse events that occurred in at least 10% of the patients treated with ofatumumab were injection-related reactions (20.2%), nasopharyngitis, headache, injection-site reaction, upper respiratory tract infection, and urinary tract infection, 2.5% of ofatumumab-treated patients experiencing serious infections compared to 1.8% in the teriflunomide-treated patients.

¹ Rahmzadeh R. et al, B cells in multiple sclerosis therapy-A comprehensive review. *Acta Neurol Scand* 2018;137:544-556. doi: 10.1111/ane.12915.

² Hauser, S. et al, Ofatumumab versus Teriflunomide in Multiple Sclerosis. *N Engl J Med*. 2020;383(6):546-557. doi: 10.1056/NEJMoa1917246.

³ <https://www.empr.com/home/news/kesimpta-ofatumumab-approved-relapsing-forms-of-multiple-sclerosis-rms/>

Impact of new MS medications

Being able to better manage and limit the frequency and impact of relapses, reduce the number of new lesions and experience less worsening of disability, can help alleviate the burden of MS on the community and the individual.

A key distinction is that ofatumumab can be self-administered by monthly injection at home rather than requiring hospital infusion. Therefore, this treatment regime provides a potentially convenient option for people with relapsing MS, particularly to those located remotely.

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.

The Health Economic Impact of MS in Australia study⁴ 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).

In addition, this study reported that on average, the quality of life of people with MS in Australia is 31% less than that of the overall Australian population. Quality of life for people with MS who are living with severe disability is 41% lower compared to people with MS with no disability. This substantially reduced quality of life is primarily driven by the impact of MS on pain, independent living, mental health and relationships.

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 improve the quality of life and alleviate the economic cost of MS to individuals, their families and the broader community.

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

⁴ Health Economic Impact of MS in Australia in 2017. https://msra.org.au/wp-content/uploads/2018/08/executive-summary_health-economic-impact-of-ms-in-australia-in-2017-report_ms-research-australia.pdf