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PBAC Secretariat
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Office of Health Technology Assessment Branch
Department of Health and Ageing
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By email to: pbac@health.gov.au

Re: Submission relating to ofatumumab (Kesimpta®) to PBAC meeting March 2024

MS Australia is writing to the Pharmaceutical Benefits Advisory Committee (PBAC) in support of the request to separate the current higher efficacy disease modifying therapies (DMTs) for multiple sclerosis (MS) into two distinct efficacy tiers.

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.

Declaration of interest

MS Australia is making this submission as we have an interest in the health and wellbeing 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 (1.7% of total revenue for FY23), 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.

MS is the most common acquired chronic neurological disease affecting young adults, often diagnosed between the ages of 20 to 40 and, in Australia, affects three times more women

than men. In MS, the body's own immune system mistakenly attacks and damages the fatty material, called myelin, around the nerves. This results in a range of symptoms that can include a loss of motor function (e.g., walking and hand and arm function, loss of sensation, pain, vision changes and changes to thinking and memory).

There is currently more than 33,000 people living with MS across the country and over 7.6 million Australians know or have a loved one with this disease[1]. 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 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.

About ofatumumab (Kesimpta®)

Ofatumumab (Kesimpta®) 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, such as ofatumumab (Kesimpta®), have been shown to be effective in the treatment of MS.

Efficacy of MS DMTs

MS Australia recognises that there are three broad categories of efficacy of DMTs, with several network meta-analyses supporting these efficacy differences[2,3,4,5]. The meta-analyses conducted indicate that monoclonal antibody treatments, including ofatumumab (Kesimpta®), ocrelizumab (Ocrevus®), alemtuzumab (Lemtrada®) and natalizumab (Tysabri®), demonstrate greater efficacy when compared to oral treatments such as fingolimod (Gilenya®). Therefore, there is justification for segregating the existing higher efficacy DMTs into two distinct efficacy tiers.

Impact on people living with MS

The availability of Pharmaceutical Benefits Scheme (PBS) listed treatments for MS has enabled people living with MS to live longer and healthier lives, while also helping to reduce the burden on Australia's healthcare system, including the impact on the National Disability Insurance Scheme (NDIS).

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.

Given MS's varied nature, no one single medication is suitable for every Australian living with MS. As such, MS Australia is grateful for the continued inclusion of all currently available DMTs on the PBS. Australians living with MS also benefit from all MS DMTs being available for use from onset, allowing people with MS and their clinical teams to treat using the induction model, of early aggressive treatment for those who need it. The medication landscape for the treatment of MS in Australia is one that is vital to preserve.

Segregating the existing higher efficacy DMTs into two distinct efficacy tiers will help ensure that new breakthrough treatments are made available to Australians living with MS, and future MS innovations are brought to the Australian market in a sustainable and timely manner.

We will continue to advocate for the inclusion on the PBS of all MS medications that have been shown to efficacious in the treatment of MS.

1. *Health Economic Impact of MS in Australia in 2021* https://www.msaustralia.org.au/wp-content/uploads/2018/08/executive-summary_health-economic-impact-of-ms-in-australia-in-2017-report_ms-research-australia.pdf

2. Li H, Hu F, Zhang Y, Li K. Comparative efficacy and acceptability of disease-modifying therapies in patients with relapsing-remitting multiple sclerosis: a systematic review and network meta-analysis. *J Neurol*. 2020 Dec;267(12):3489-3498. doi: 10.1007/s00415-019-09395-w.

3. Siddiqui MK, Khurana IS, Budhia S, Hettle R, Harty G, Wong SL. Systematic literature review and network meta-analysis of cladribine tablets versus alternative disease-modifying treatments for relapsing-remitting multiple sclerosis. *Curr Med Res Opin*. 2018 Aug;34(8):1361-1371. doi: 10.1080/03007995.2017.1407303

4. Śladowska K, Kawalec P, Holko P, Osiecka O. Comparative safety of high-efficacy disease-modifying therapies in relapsing-remitting multiple sclerosis: a systematic review and network meta-analysis. *Neurol Sci*. 2022 Sep;43(9):5479-5500. doi: 10.1007/s10072-022-06197-3.

5. McCool R, Wilson K, Arber M, Fleetwood K, Toupin S, Thom H, Bennett I, Edwards S. Systematic review and network meta-analysis comparing ocrelizumab with other treatments for relapsing multiple sclerosis. *Mult Scler Relat Disord*. 2019 Apr;29:55-61. doi: 10.1016/j.msard.2018.12.040.