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PBAC Secretariat
MDP 952
Pharmaceutical Evaluation Branch
Department of Health and Aged Care
GPO Box 9848
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By email to: pbac@health.gov.au

Re: Submission relating to ublituximab (Briumvi®) to PBAC meeting May 2025

MS Australia is writing to the Pharmaceutical Benefits Advisory Committee (PBAC) in support of the request to include ublituximab (Briumvi®) on the Pharmaceutical Benefits Scheme (PBS) for the treatment of people living with relapsing remitting multiple sclerosis (MS).

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 (3% of total revenue for FY24), with an interest in MS in the form of grants for projects and support of our national MS research scientific conference.

About 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 are currently more than 33,300 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 ublituximab (Briumvi®)

Ublituximab (Briumvi®) is a monoclonal antibody that targets CD20, a molecule found on a subset of B cells, and acts as a B cell-depleting agent[2,3]. B cells have an important role in the pathology of MS as they produce pro-inflammatory molecules[3]. Monoclonal antibody therapies targeting CD20, such as ocrelizumab and ofatumumab, have been shown to be effective disease-modifying therapies (DMTs) for MS[4]. Ublituximab targets a different epitope of CD20 that other anti-CD20 monoclonal antibody therapies target[2].

Ublituximab is the first anti-CD20 antibody that is administered intravenously twice per year after the initial dose and with an infusion time of one hour[3]. This is a significantly shorter duration of administration compared to the monoclonal antibody therapies ocrelizumab and alemtuzumab and requires less frequent dosing than needed for ofatumumab and natalizumab[5,6].

Ublituximab was approved by the US Food and Drug Administration in December 2022[7] and by the European Medicines Agency[8] in March 2023 for the treatment of relapsing remitting MS[5].

Clinical trials for ublituximab (Briumvi®)

Recent phase 3 clinical trials (ULTIMATE I and ULTIMATE II) showed ublituximab resulted in significantly lower relapse rates at 96 weeks compared to oral teriflunomide (a medication that blocks lymphocytes from multiplying) combined with intravenous placebo[2]. Individuals with MS receiving ublituximab also had significantly fewer new MRI lesions than those receiving teriflunomide. There were no differences between the two treatments for brain volume or progression of disability.

While most (89.2%) of the ublituximab group experienced an adverse event, most were manageable. Nearly half had reactions related to the infusion. Other adverse events such as headache (34.3%), nasopharyngitis (18.3%), pyrexia (13.9%) and nausea (10.6%) were the most common following infusion-related reactions.

Most of the participants (91.4%) in the teriflunomide group also experienced adverse events, the most common being headache (26.6%), nasopharyngitis (17.9%), alopecia (15.3%), infusion-related reactions (how placebo was administered, 12.2%) and diarrhoea (10.6%).

There were three deaths in the ublituximab group due to pneumonia, encephalitis and salpingitis after an ectopic pregnancy and which were related to infections[3].

Comparing ublituximab (Briumvi®) to other monoclonal antibody therapies

A systematic review and network meta-analysis published in 2024 reported that ublituximab has similar effects on relapse rate and disability progression to other high-efficacy monoclonal antibody treatments, including ocrelizumab, ofatumumab, natalizumab and alemtuzumab[9].

Overall, ublituximab offers comparable efficacy to other high-efficacy monoclonal antibody therapies in terms of reducing relapse rates and slowing disability progression, making it a valuable treatment option for people with relapsing forms of MS.

Impact on people living with MS

MS Australia supports affordable access to all proven treatment options to increase the opportunity for people with MS to access effective therapy. We strongly advocate for the PBS listing of ublituximab for people living with relapsing remitting MS.

Effective management of MS can limit the frequency and impact of relapses, reduce the number of new lesions, and reduce disability progression, thereby alleviating the burden of MS on the community and the individual.

Finding the right treatment for each person living with MS is crucial, as suboptimal treatment can lead to an increased symptoms and irreversible accumulation of disability. This, in turn, places a greater burden on the healthcare system and reduces the quality of life for patients and their families.

Given the varied nature of MS, **no single medication is suitable for every Australian living with MS.** MS Australia is grateful for the continued inclusion of all currently available DMTs on the PBS.

The availability of ublituximab on the PBS would improve the quality of life for people living with MS and help reduce the burden on Australia's healthcare system, including the impact on the National Disability Insurance Scheme (NDIS). MS Australia will continue to advocate for the inclusion on the PBS of all medications that have been shown to be efficacious in the treatment of MS.

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

References

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