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PBAC Secretariat
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Pharmaceutical Evaluation Branch
Department of Health and Aged Care
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By email to: commentsPBAC@health.gov.au

**Re: Submission relating to ocrelizumab (Ocrevus®) via subcutaneous delivery for relapsing-remitting multiple sclerosis to PBAC meeting July 2025**

MS Australia is writing to the Pharmaceutical Benefits Advisory Committee (PBAC) in support of the request to include ocrelizumab (Ocrevus®) via subcutaneous (SC) delivery on the Pharmaceutical Benefits Scheme (PBS) for the treatment of people living with relapsing-remitting multiple sclerosis (RRMS).

MS Australia is Australia's national multiple sclerosis (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, is 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 ocrelizumab (Ocrevus®)**

Ocrelizumab is a humanised monoclonal antibody that targets CD20, a molecule found on a subset of B cells, and acts as a B cell-depleting agent.[2] B cells have an important role in the pathology of MS by producing pro-inflammatory molecules, stimulating immune T cells that attack the brain, and damaging myelin-producing cells (oligodendrocytes) and nerve cells in the brain and spinal cord.

Two large clinical trials (OPERA I and OPERA II)[4] showed that intravenous (IV) ocrelizumab to significantly reduced relapse rates and disability progression, when compared to SC interferon beta-1a.

The Therapeutic Goods Administration (TGA) approved the registration of IV ocrelizumab for the treatment of RRMS and primary progressive MS in July 2017.[5,6] It was listed on the PBS in February 2018 as a treatment for RRMS.[7]

**Clinical trials for SC ocrelizumab (Ocrevus®)**

A recent phase III trial (OCARINA II)[10,11] that compared SC and IV administered ocrelizumab in people with relapsing MS or primary progressive MS showed that the two treatments had similar outcomes. Both treatments nearly completely suppressed MRI lesion activity by week 12 and this was sustained over the 48 weeks of the trial. Also, over 97% of participants in both the SC and IV ocrelizumab arms were free of relapses up to week 48[11]. Disability as measured by the Expanded Disability Status Scale remained unchanged over the trial in both treatment arms[11].

Both treatment delivery methods led to fast and sustained B cell depletion and were well tolerated. By week 48, both treatments reduced serum neurofilament light chain levels to that found in people without MS. No new safety concerns were identified for the SC method of administration.[10]

SC ocrelizumab was approved by the US Food and Drug Administration in September 2024 to treat RRMS[8] and by the European Medical Agency in June 2024, to treat RRMS and primary progressive MS.[9]

## Impact on people living with MS

A key distinction of SC ocrelizumab is that it expands the clinical settings, beyond infusion centres, where patients can be treated. Many patients may have limited availability to attend infusion centres, where infusion of ocrelizumab can take up to three hours.

IV ocrelizumab is administered initially as two 300mg doses two weeks apart with subsequent 600mg doses administered every six months[12]. In contrast, SC ocrelizumab is administered as a 920mg dose every six months, taking only 10 minutes each time, with around one hour of monitoring following the first injection[12].

The SC option would allow patients to attend their local healthcare professional for administration. This treatment route provides a potentially convenient option for people with RRMS, particularly for those located in rural or remote regions, who would not have to travel long distances to infusion centres to receive their treatment.

Additionally, 80.4% of people with MS who participated in the OCARINA II trial who had experienced both IV and SC ocrelizumab **preferred the SC form[13]**.

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. MS was estimated to cost the Australian community $2.5 billion in 2021,[1] or $73,457 per person living with MS.

Given the varied nature of MS, **no single medication is suitable for every Australian living with MS.** 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.

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 SC ocrelizumab for people living with RRMS.

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

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