

MS Research Australia is writing to support the inclusion of ocrelizumab (Ocrevus) on the Pharmaceutical Benefits Scheme (PBS) for people with primary progressive MS.

As the largest national not-for-profit organisation dedicated to funding MS discoveries and coordinating MS research in Australia, we are proud to advocate on behalf of people affected by this disease. One area of particular importance to MS Research Australia and the MS community is the affordable availability of treatments that have been shown to be effective in clinical trials to reduce the impact of MS. MS Research Australia therefore encourages this committee to support the inclusion of ocrelizumab on the Pharmaceutical Benefits Scheme (PBS) for the treatment of primary progressive MS. The affordable availability of evidence-based treatments for progressive forms of MS is the greatest unmet need facing the MS community in Australia. In contrast, many European countries, as well as the UK, Canada, USA, and a selection of South American and Middle Eastern countries already provide a subsidy for ocrelizumab for people with primary progressive MS.

Primary progressive MS affects 10-15% of people with MS. In primary progressive MS, people experience a progressive worsening of symptoms and disability, without the periods of recovery or remission that are experienced by people with relapsing remitting MS. In primary progressive MS, irreparable damage is caused to the central nervous system. This results in an individual gradually losing function and increasing their reliance on the health and disability care systems together with a significant loss of quality of life for both patients and their families.

In Australia, there are currently 12 disease modifying treatments available for people with relapsing remitting MS, all of which are listed on the PBS. Ocrelizumab is the first and only evidence-based therapy available to specifically treat people with primary progressive MS. The inclusion of ocrelizumab on the PBS for the treatment of primary progressive MS would bring hope to the lives of many people with primary progressive MS and their families. Currently, individuals with primary progressive MS are likely to be receiving no treatment at all and as a result feel neglected and frustrated. The lack of options may also result in many being driven to utilise high risk, unproven therapeutic options and strategies, or they may be receiving other MS medications that are costly but have not been proven to be beneficial for people with primary progressive MS.

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. MS costs the Australian community over \$1.75 billion per year <sup>1</sup>. The total cost of MS increases with increasing disability severity. In 2017, the costs more than tripled in people with MS with severe disability (\$114,813) compared to those with no disability (\$30,561) <sup>1</sup>. The impact of MS on quality of life can be equivalent to that experienced by people with terminal metastatic cancer, chronic kidney disease and severe heart disease <sup>1</sup>.





Ocrelizumab is a humanised monoclonal antibody that reduces the numbers of B cells in the immune system. These cells are thought to be involved in the continued demyelination that contributes to the increasing disability in people with primary progressive MS. Ocrelizumab is given as two 300 mg infusions 14 days apart, every 24 weeks.

Ocrelizumab has been shown to slow the continued progression in disability that is experienced by people with primary progressive MS compared to placebo. In a phase III clinical trial, people with primary progressive MS either received ocrelizumab or placebo every 24 weeks for at least 120 weeks (minimum five doses) <sup>2</sup>. By 24 weeks post-first treatment, 29.6% of people taking ocrelizumab had confirmed disability progression, compared to 35.7% of people in the placebo group. This is a reduction of 25% in the relative risk of disability progression. The trial results also showed that people taking ocrelizumab had a lower number of active lesions, fewer new lesions, and lower overall brain volume loss compared to people taking placebo. Whilst this is a modest delay in disability, the effects can be life changing for the people with primary progressive MS, their families, and the Australian community as a whole, allowing the individual to remain independent and potentially in employment for as long as possible. An extension of physical and mental functions and quality of life is greatly needed for people with primary progressive MS, and ocrelizumab represents a potential method to achieve this.

As with all MS medications, the efficacy, side effect profiles and tolerability of a drug can vary greatly between individuals. Ocrelizumab has been shown to have a good safety profile and to be largely well-tolerated by people with MS <sup>2</sup>. The most common side effect was infusion-related reactions, which occurred in 39.9% of people being treated with ocrelizumab, and often decreased with subsequent doses. Neoplasms occurred in 2.3% of participants receiving ocrelizumab. 71.4% of patients on ocrelizumab and 69.9% of patients on placebo reported infections, which included nasopharyngitis, urinary tract infection, influenza, and upper respiratory tract infections. There was no significant difference in the rates of serious adverse events (20.4% ocrelizumab and 22.2% placebo) and serious infections (6.2% ocrelizumab and 5.9% placebo) between each of the groups.

MS Research Australia supports affordable access to all proven treatment options to increase the opportunity for people with MS and their doctors to find effective therapies suited to their individual circumstances. Reducing disease progression will improve quality for people with MS and their loved ones, enabling their full participation in social and family life, and employment.

MS Research Australia appreciates the opportunity to make this submission and applauds the Committee for seeking the views of people with MS and the wider community as part of the process of considering MS treatments for inclusion on the PBS.

- 1) Health Economic Impact of MS in Australia in 2017. [https://msra.org.au/wp-content/uploads/2018/08/health-economic-impact-of-ms-in-australia-in-2017\\_ms-research-australia\\_web.pdf](https://msra.org.au/wp-content/uploads/2018/08/health-economic-impact-of-ms-in-australia-in-2017_ms-research-australia_web.pdf)



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- 2) Montalban X, Hauser SL, Kappos L, Arnold DL, Bar-Or A, Comi G, de Seze J, Giovannoni G, Hartung HP, Hemmer B, Lublin F, Rammohan KW, Selmaj K, Traboulsee A, Sauter A, Masterman D, Fontoura P, Belachew S, Garren H, Mairon N, Chin P, Wolinsky JS; ORATORIO Clinical Investigators. [Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis](#), *N Engl J Med*. 2017 Jan 19;376(3):209-220 doi: 10.1056/NEJMoa1606468