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

25 September 2017

Re: OCREVUS (Ocrelizumab) for primary progressive MS – November 2017 PBAC Agenda

As the largest organisation dedicated to funding and coordinating multiple sclerosis (MS) research in Australia, we are proud to advocate on behalf of people affected by MS. Decades of research have led to significant improvements in our understanding of MS, and how it can be best be treated and managed. It is of particular importance to MS Research Australia that this research is translated and implemented into the availability of affordable and effective treatments that can reduce the impact of the disease on individuals and the Australian community as a whole. As such MS Research Australia supports the affordable availability of all efficacious and safe treatment options that have been show in clinical trials to benefit people with MS and related disorders. MS Research Australia therefore encourages this committee to support the inclusion of Ocrevus on the Pharmaceutical Benefits Scheme (PBS) for the treatment of Primary progressive MS (PPMS).

The availability of evidence-based treatments for progressive forms of MS is the greatest un-met need facing the MS community world-wide.

In Australia there are currently 13 disease modifying treatments available for people with relapsing remitting MS, all of which are listed or are recommended for listing on the PBS. Ocrevus is the first and only evidence based therapy specifically for treating PPMS. The inclusion of Ocrevus on the PBS list for the treatment of PPMS would bring hope to the lives of many people with PPMS and their families. Currently, individuals with PPMS 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 PPMS.

PPMS affects 10-15% of people with MS. In PPMS, 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 PPMS, 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.

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In previously commissioned research (https://msra.org.au/wp-content/uploads/2016/03/Economic-Impact-of-MS-in-2010-Full-Report-v2-1.pdf), we have demonstrated that the economic costs of MS significantly increase as disability increases. This research found a substantial increase in personal costs when the disability of a person with MS becomes severe. This also tends to occur at a time when income is decreasing causing a significant burden for the individual and family. Lost productivity for the person with MS and those providing informal care to them rises considerably as disability increases. The resulting total direct and indirect costs to the individual and the Australian community rises to over $71,000 per person with MS per year for a person with severe disability, compared to just $26,700 for those with only mild disability.

Ocrevus 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 PPMS. Ocrevus is given as two 300 mg infusions 14 days apart, every 24 weeks.

In clinical trials, Ocrevus has been shown to slow the continued progression in disability that is experienced by people with PPMS compared to placebo. In a clinical trial, people with primary progressive MS received at least five doses of Ocrevus and remained on the treatment for at least 120 weeks (5 doses). By 24 weeks post-first treatment 29.6% of people taking Ocrevus had confirmed disability progression, compared to 35.7% of people in the placebo group. This is a reduction in the relative risk of disability progression of 25%. The trial results also showed that people taking Ocrevus had lower number of active lesions, fewer new lesions, and lower overall brain volume loss compared to placebo. Whilst this is a modest delay in disability, the effects can be life changing for the people with PPMS, 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 PPMS, and Ocrevus 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. Ocrevus has been shown to have a good safety profile and to be largely well tolerated by people with MS. The most common side effect, infusion-related reactions, occurred in 39.9% of people being treated with Ocrevus, and often decreased with subsequent doses. 71.4% of patients on Ocrevus reported infections, which included nasopharyngitis, urinary tract infection, influenza, and upper respiratory tract infections. Serious infections occurred in 6.2% of people receiving Ocrevus treatment, and neoplasms occurred in 2.3% of the trial participants.

MS Research Australia supports any proven treatments that will reduce the progression of disability and improve the quality of life of people with MS. This in turn will affect those around them – their family members and carers. We strongly urge the committee to recommend that this medication is made affordably available to people with primary progressive MS who, for far too long have been left without any treatment options to slow the destruction caused by this insidious form of MS.

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

Table 3.6 Costs of MS by severity

	Mild	Moderate	Severe	Not stated	Total
Per person with MS ($'s)					
Direct costs - personal	$2,062	$4,097	$7,380	$3,788	$3,697
Direct costs - community / government	$10,181	$11,098	$12,042	$9,304	$10,721
Nursing home and equivalent costs*	$4,384	$4,384	$4,384	$4,384	$4,384
Informal care	$3,395	$9,569	$11,111	$6,227	$6,857
Indirect costs	$16,347	$29,743	$30,388	$20,354	$23,286
Total costs	**$36,369**	**$58,890**	**$65,305**	**$44,057**	**$48,945**
Total ($000's)					
Direct costs - personal	$19,345	$28,787	$24,831	$5,414	$78,376
Direct costs - community / government	$95,492	$77,984	$40,516	$13,297	$227,288
Nursing home and equivalent costs[a]	$41,118	$30,806	$14,750	$6,266	$92,941
Informal care	$31,843	$67,238	$37,383	$8,900	$145,365
Indirect costs	$153,319	$209,004	$102,245	$29,090	$493,657
Total costs	**$341,117**	**$413,819**	**$219,724**	**$62,967**	**$1,037,627**

Notes: Mild severity includes EDSS levels 1 - 3, Moderate includes 4 – 6, Severe includes levels 6.5 – 9.

[a] Nursing home costs are not broken down by MS severity. Nursing home costs are available for the total population only. Total cost in each category is calculated from the category population and the overall mean cost. Therefore no inference should be made for the difference in cost between categories

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Table 3.7 Cost of MS by EDSS

	0-1	2-3	4-5	6	6.5	7-9	NC	Not stated	Total
Per person with MS ($'s)									
Direct costs - personal	$1,237	$2,754	$3,511	$4,608	$4,859	$10,338	$2,792	$3,788	$3,697
Direct costs - community/ government	$10,517	$9,660	$11,912	$10,387	$9,567	$14,944	$10,385	$9,304	$10,721
Nursing home and equivalent costs*	$4,384	$4,384	$4,384	$4,384	$4,384	$4,384	$4,384	$4,384	$4,384
Informal care	$849	$5,721	$6,070	$12,623	$11,442	$10,722	$5,244	$6,227	$6,857
Indirect costs	$9,801	$19,481	$23,969	$34,784	$29,547	$31,375	$27,050	$20,354	$23,286
Total costs	**$26,788**	**$42,001**	**$49,846**	**$66,786**	**$59,799**	**$71,764**	**$49,855**	**$44,057**	**$48,945**
Total ($000's)									
Direct costs - personal	$5,341	$9,432	$11,500	$17,287	$8,825	$16,006	$4,572	$5,414	$78,376
Direct costs - community/ government	$45,407	$33,079	$39,016	$38,968	$17,377	$23,138	$17,006	$13,297	$227,288
Nursing home and equivalent costs[a]	$18,928	$15,012	$14,359	$16,447	$7,963	$6,788	$7,179	$6,266	$92,941
Informal care	$3,664	$19,591	$19,880	$47,358	$20,782	$16,601	$8,588	$8,900	$145,365
Indirect costs	$42,313	$66,707	$78,505	$130,499	$53,665	$48,579	$44,299	$29,090	$493,657
Total costs	**$115,653**	**$143,820**	**$163,259**	**$250,560**	**$108,612**	**$111,112**	**$81,644**	**$62,967**	**$1,037,627**

Abbreviations: NC, not classified.

Notes: [a]Nursing home costs are available for the total population only. Total cost in each category is calculated from the category population and the overall mean cost. Therefore no inference should be made for the difference in cost between categories.