Multiple Sclerosis New Zealand

Adrienne Martin
Therapeutic Group Manager
PHARMAC
PO Box 10-254
Wellington 6143

22 May 2017

Dear Adrienne,

RE: Request for consideration of funding Ocrelizumab for Relapsing Remitting MS from The Multiple Sclerosis Society of New Zealand (Inc)

The Multiple Sclerosis Society of New Zealand is aware that Roche NZ is making a submission to request Ocrelizumab be listed on the Pharmaceutical Schedule for the treatment of Relapsing Remitting MS due to be reviewed at the August PTAC meeting. We are writing in support of this application.

We would like to note that while this submission is focussed on the funding for Relapsing Remitting MS (RRMS) this in no way signals that we do not fully support the funding for Primary Progressive MS (PPMS). Prior to the August meeting we will also submit a request for funding on the latter however it is our understanding that Relapsing Remitting will be the only form of MS that is under review at the upcoming August PTAC meeting to which this letter addresses.

MS organisations and clinicians around the world endorse the view points that to provide the optimal level of care to PwMS countries should:

- Make the full range of disease-modifying therapies available to people with active relapsing forms of MS, regardless of their treatment history, to speed up adoption of the most appropriate treatment strategy that optimises the effectiveness and safety for each individual.
- Endorse the rapid switching to another DMT if monitoring reveals a suboptimal response in order to maximise the chance of achieving the best possible outcome for every person with MS who would be at risk of inflammatory disease activity if they were not receiving treatment.
- Implement a shared decision-making process that embodies dialogue between people with MS and healthcare professionals. A well-informed and proactive collaboration between people with MS and their healthcare team is vital to successful management of the disease.

It is under these recommendations and on the evidence based benefits shown through human trials that we endorse the funding of Ocrelizumab for RRMS in NZ.

Two trials involving 1656 people with RRMS, 821 of which received the proposed treatment, showed clear demonstrable evidence that relapses were reduced, the volume of brain lesions were significantly decreased and the reduction in disability progression were all attributed to the use of Ocrelizumab. All of these outcomes have the potential to have a profound and life-improving effect of PwMS in NZ.

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Relapses

Trials OPERA 1 and OPERA 2 clearly showed a 46% and 47% lower rate of relapses compared to it interferon beta-1a trial comparator. The reduction in relapses reduces the risk of people with RRMS acquiring irreparable disability, progressing further on the EDSS scale risking disqualification from treatment under the current criteria and therefore enabling them to continue working, supporting their families, improving their well-being, whilst also mitigating potential financial impacts on the individual, health and social welfare systems.

Research released in January 2017 shows that in a European based study, 'New insights into the burden and costs of multiple sclerosis in Europe', the average cost of a relapse to the health system is 2188Euro (NZ$3360) based on Purchasing Power. While we do not have the current cost to the NZ health system for relapses this can be used as a reliable comparison with the data being collated from 16 European countries. All efforts should be taken to reduce the effects of the disease and the risks of relapses. While many relapses will not have a long term effect on a persons disability the cost of a relapse to the health system and the individual can be significant and all effort should be made to reduce the risk of occurrence.

Disability

Both studies clearly demonstrated that Ocrelizumab lowered the risk of disability progression by 40%. Disability improvement was also shown to be 33% higher with use and between 47.9% and 47.5% of the Ocrelizumab recipients had no evidence of disease activity over the trial period compared to 29.2% and 25.1% of those on the interferon. These are significant improvements and reductions in disability. The fear of disability and what the unknown future course of the condition has a profound effect on the well-being of a person with MS. Treatments such as Ocrelizumab which show significant reductions in disability progression, disease activity and a reduced risk of disability should be supported and funded treatments.

Lesion Reduction

The two trials reported 94% and 95% lower number of T1 gadolinium enhancing lesions in those patients MRIs who were being administered Ocrelizumab than the interferon recipients and a 77% and 83% lower number of new or growing T2 hyperintense lesions was also noted. The study also showed that the longer the patients underwent treatment the number of new lesions decreased. This demonstrates the huge potential benefits that Ocrelizumab has to NZ PwMS in reducing the occurance of new lesions which may have an irreparable and disabling effect on people.

Method of provision

Ocrelizumab is given intravenously on days 1 (300-mg), 15 (300-mg) and then every 24 weeks (600-mg). For many PwMS this will mean less visits to the hospital than those receiving current intravenous DMDs monthly and in turn less infusion clinic appointments for DHBs.

Annual reviews will be required as with the current treatments. Regular monitoring of the disease and recording of information formally are a key part of any successful disease management strategy.

Choice and informed access

Offering a full range of therapies can improve the chances of finding the best option for each person with MS. With greater choice neurologists, in consultation with their patients, will be able to investigate the best course of treatment suitable with the person's lifestyle and risk factors. There is currently no one treatment that is best suited to everyone. Until that time it is important that a full range of DMTs are available in NZ with the opportunity for PwMS to switch to alternative therapies should the effectiveness of a current option reveal a suboptimal response. This switching should be able to occur in an expedited, time-sensitive manner to reduce the risk of not qualifying for further treatment. Neurologists and PwMS need the scope and flexibility to be able to find the best option for the individual.

It is important that health professionals take the time to educate people with MS about combined strategies to manage their disease. This should include a combination of early treatment where clinically appropriate alongside lifestyle adaptations to reach the goal of minimising disease activity while optimising safety.

The importance of informed choice is clearly shown when accessing the potential risks of these newer treatments. In Ocrelizumab while there has been no evidence of the potentially life threatening JCV Virus other risks were highlighted through the trials. Notably a higher than normal risk of herpes reactivation and of the neoplasms, especially breast cancer. Due this these increased risk regular monitoring, consultations with patients and increased communications with primary health care providers should be endorsed. Neurologists will need to ensure that they are providing their patients with comprehensive information regarding the risks and benefits of these treatments to allow them to make informed choices. Pre-treatment tests and reviews of a patients history for predispositions, where possible, for cancer, particularly breast cancer, and herpes should be required for people considering using Ocrelizumab, just as the JCV virus is tested for Tysabri. While these medical conditions are not uncommon for General Practitioners to see in their practices it will be important to ensure they are aware that they are potential side effects their patients may present with to catch them in their early stages. GPs can play an integrated role in supporting people with MS to make informed decisions and provide care beyond the neurologist.

Expansion to the funding criteria

The patient group in the two human trials included people with RRMS up to EDSS score 5.5. Evidence suggests that the current funding criteria for the MS treatments is too restrictive for Ocrelizumab and we ask PHARMAC to consider expanding the criteria to align with the evidence.

We thank you for considering Ocrelizumab to be listed on the Pharmaceutical Schedule. We fully support the listing for RRMS and in the near future will also submit for funding for PPMS. We have received a positive interest from the MS Community in seeing Ocrelizumab becoming available for funding and we hope the application will be looked upon favourably for the benefit of people with Multiple Sclerosis in New Zealand.

Kind Regards,

Amanda Keefe
National Manager

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