Multiple Sclerosis Research Australia
1300 356 467 • enquiries@msra.org.au • www.msra.org.au
Level 19, Northpoint 100 Miller Street • North Sydney • NSW 2060
PO Box 625 • North Sydney • NSW 2059
ABN 34 008 581 431

Lemtrada second dosing PBAC submission – November 2018

MS Research Australia is writing to support the inclusion of a second round of alemtuzumab infusions (Lemtrada) on the Pharmaceutical Benefits Scheme (PBS) for people with relapsing multiple sclerosis (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.

The inclusion of the additional dosage of alemtuzumab on list of PBS supported treatments for MS is vital to maximising the availability of evidence based treatments for people with MS. The heterogeneous nature of MS means no single disease modifying treatment is likely to be effective for all cases of MS. Therefore, it is vital that there is an extensive arsenal of available treatments to allow optimal treatment for as many patients as possible. Suboptimal treatment can lead to MS relapses causing irreparable damage to the central nervous system leading to an increased burden on the healthcare system and a further reduction in the quality of life of patients and their families.

Since the original clinical trials into alemtuzumab longer term data on outcomes has been collected in long term extension studies. In these extension studies retreatment was available as needed. In the CARE-MS I cohort, 64% of patients required only the initial two courses of alemtuzumab, with 23%, 8%, 3%, and <1% receiving a third, fourth, fifth, or sixth course, respectively, over 6 years. Similarly, in CARE-MS II cohort, 55% of patients required the initial two courses of alemtuzumab with 30%, 12%, 2%, and 1% receiving a third, fourth, fifth, or sixth course, respectively. Of the patients from CAMMS223 who entered the CARE-MS extension, 33% received only the initial two courses of alemtuzumab over 10 years; 43%, 12%, and 10% received three, four, or five courses of alemtuzumab, respectively. Across these three studies, investigators cited relapse as the most common reason for retreatment.

The two CARE-MS clinical trials showed that after two years 85-89% of patient has stable or improved disabilities as demonstrated by the Expanded Disability Status Scale (EDSS). After six years this was 77-81%. An analysis of CARE-MS I and II estimated the proportion of patients who converted from relapsing remitting MS to secondary progressive MS (SPMS) following alemtuzumab treatment to be low, with rates of conversion over 6 years in CARE-MS I of 1.1% and in CARE-MS II of 3.7%. Of note, the rate of SPMS conversion of people with relapsing remitting MS in the clinical registry, MSBase, was 18% over 5.8 years follow up.

The data from the original clinical trials and the associated extension studies suggest that some people with MS do require additional courses of treatment and that the results show that patients do benefit from alemtuzumab treatment, including delaying conversion into secondary progressive MS. As such, MS Research Australia supports the inclusion of additional doses of alemtuzumab on the PBS to ensure affordable access for patients who require it.

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 the frequency of disabling relapses will improve quality for people with MS and their loved ones, enabling their full participation in social and family life, and employment.