

Buenos Aires February 27<sup>th</sup>, 2019

Dear Expert Committee,

We write to support the addition of Glatiramer Acetate, Fingolimod and Ocrelizumab to the list of disease modifying therapies in the World Health Organization (WHO) Model Lists of Essential Medicines for adults with Multiple Sclerosis (MS). There is an urgent need to expand access to these therapies, which are used to treat MS in the different stages of the disease. Since there are no drugs for the treatment of MS in the EML, this would help patients with this devastating disease (MS is the second cause of disability in young adults after car accidents) could have access to these drugs.

1) Glatiramer Acetate (GA) is classified as a non-biological complex drug (NBCD) and GA is a mixture of peptide copolymers containing four specific amino acids in a defined ratio. The amino acids present in glatiramer acetate are L-glutamic acid, L-lysine, L-alanine and L-tyrosine with an average molar ratio of 0.141, 0.338, 0.427 and 0.095 respectively. GA is approved by FDA and EMA to reduce the frequency of relapses and indicated for the treatment of patients with relapsing-forms of MS. GA has a high safety profile and use in pregnancy, availability of high quality generics. Administered through regular subcutaneous injections and has a long history of use.

2) Fingolimod: The first FDA approval oral drug to treat relapsing-remitting MS in adults patients (2010) and the first approved to treat MS in paediatric patients (2018). Fingolimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of MS to reduce the frequency of relapses and to delay the accumulation of physical disability. The tolerability past first dose makes Fingolimod a safety drug despite some additional risk. It is administered orally once a day.

3) Ocrelizumab is a CD20-directed cytolytic antibody indicated for the treatment of patients with relapsing or primary progressive forms of MS. It presents low monitoring requirements, good safety profile, though in use for less time. An infusion therapy that offers high efficacy, but with some additional risk.

We believe that the inclusion of these 3 drugs in the list covers the spectrum of different stages of the disease in our country including patients with recent diagnosis or mild clinical forms (Glatiramer Acetate); active patients and / or failure to other treatments and pediatric patients with MS (Fingolimod); and very active patients or with primary progressive forms (Ocrelizumab). These three DMTs put forward is the minimum number of DMTs required for adequate treatment. The application is not intended to suggest that these are the only three therapies of value in MS or to create a treatment algorithm

We agree with MSIF to maintain the principle of treatment choice for people with MS, then assessing efficacy, safety, liveability, quality of evidence.

Sincerely,

Dr. Jorge Correale

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