Funding application for widened access to Disease Modifying Treatments (DMTs) for MS

There are specific subgroups of patients that the MS Society would like to propose widening funded access to, and these are detailed below.

1. Clinically isolated syndrome (CIS) that fulfils the McDonald 2010 criteria for diagnosis of MS

The Special Authority criteria for DMTs for MS specify that a patient must have a diagnosis of Clinically Definite Multiple Sclerosis (CDMS), an Expanded Disability Status Scale (EDSS)\(^1\) score of 0-4 and the patient must have experienced at least 1 significant relapse in the previous 12 months or 2 in the past 24 months; and must have evidence of new inflammatory activity on an MR scan within the past 24 months.

Patients with CIS who fulfil the McDonald 2010 diagnostic criteria for MS (one attack and have MRI evidence of dissemination in time and space)\(^2\) are not eligible for funded DMTs.

The MS Society considers that access to funded DMTs should be widened for patients with CIS who fulfil the McDonald 2010 criteria.

The MS Society considers that treating patients who have early MS with DMTs reduces the risk of a second attack and further disability.

The evidence provided by the MS Society to support a benefit from DMTs for patients with CIS is as follows:


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• Jacobs, L. D. et al. Intramuscular interferon beta-1a therapy initiated during a first
demyelinating event in multiple sclerosis. CHAMPS Study Group. N. Engl. J.
• Kappos, L. et al. Treatment with interferon beta-1b delays conversion to clinically
definite and McDonald MS in patients with clinically isolated syndromes.
• Miller, A. E. et al. Oral teriflunomide for patients with a first clinical episode
suggestive of multiple sclerosis (TOPIC): a randomised, double-blind, placebo-
• Tintore, M., Rovira, A. & Otero-Romero, S. Factors that determine disease
course: early changes contribute to predict long-term prognosis: the ‘Barcelona

2. **Amending the stopping criteria to EDSS 4.5 for all patients irrespective of EDSS
score at entry.**

The Special Authority criteria for DMTs require funded treatment be stopped if
patients have an increasing relapse rate or if there is progression of disability by
any of the following EDSS points (the first point is the EDSS at treatment entry,
the second when treatment stops):

- 0–3.0, 1.0–3.0, 1.5–3.5, 2.0–4.0, 2.5–4.5, 3.0–4.5, 3.5–4.5, 4.0–4.5

The MS Society considers allowing for DMTs until EDSS 4.5, irrespective of the
EDSS at treatment entry, reduces the risk of accumulating further disability and
relapses. In addition, it considers that there may be other health benefits with
regards to reduced fatigue and improved cognition by allowing treatment until
EDSS 4.5.

The evidence provided from the MS Society to support a benefit for widening
access to DMTs in this group is as follows:

- Lizak, N. et al. Highly active immunomodulatory therapy ameliorates
accumulation of disability in moderately advanced and advanced multiple
313976
- Hauser, S. L. et al. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple

3. **Amending the definition for ‘significant relapse’ in the Special Authority criteria for
all MS treatments**

The Special Authority criteria specifies that a significant relapse ‘must last at
least one week’.

The MS Society considers that the definition used for a ‘significant relapse’
should be changed to ‘must last at least 24 hours’. The MS Society considers
that amending this requirement would ensure early access to DMTs to prevent
disability accumulation and would align with international best practice.

The evidence provided from the MS Society to support amending the definition
for a ‘significant relapse’ is as follows:

4. Use of an alternative measurement scale to assess effectiveness of treatment.

The Special Authority criteria for DMTs for MS utilises the EDSS as a way of measuring disability in MS to determine entry and stopping criteria for access to funded treatments. The EDSS quantifies disability in eight Functional Systems plus ambulation (mobility), with Functional System Scores in each of these functional systems: pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, cerebral (or mental), and other. EDSS scores range from 0 to 10, in 0.5 increments. The higher the score, the higher the level of disability.

The MS Society considers DMTs for MS provide health benefits for non-physical symptoms of MS such as fatigue and cognition and that there are other disability scales available which would be more suitable than EDSS alone.

The MS Society has identified three scales, to assess effectiveness of treatment, as possible alternatives to the EDSS scale, especially beyond solely ambulation. These are the Multiple Sclerosis Functional Composite (MSFC) scale, the Multiple Sclerosis Impact Profile (MSIP) and the Performance Scales (PS).

The evidence provided from the MS Society to support a benefit of using an alternative scale to assess effectiveness of treatment is as follows: