Fingolimod 0.5mg Capsules

Prescriber Criteria: Consultant Neurologist

Outpatient and Inpatient use:

1. Multiple Sclerosis

Single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups following treatment with dimethyl fumarate:

- These patients may be defined as those who have failed to respond to a full and adequate course (normally at least six months of treatment) of beta-interferon as well as an adequate therapeutic trial with dimethyl fumarate. Patients should have had at least 1 relapse in the previous year while on therapy, and have at least 9 T2-hyperintense lesions in cranial MRI or at least 1 Gadolinium-enhancing lesion. A "non-responder" could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.

or

- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

or

- Patients who are intolerant to dimethyl fumarate

Duration of Approval:

1 year initially
2 years thereafter