



## Final Appraisal Recommendation

Advice No: 3516 – December 2016

### Fingolimod (Gilenya<sup>®</sup>▼) 0.5 mg hard capsules

Submission by Novartis Pharmaceuticals UK Ltd

#### Recommendation of AWMSG

Fingolimod (Gilenya<sup>®</sup>▼) is recommended as an option for use within NHS Wales for use as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient group:

- 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.

This recommendation applies only in circumstances where the approved Patient Access Scheme (PAS) is utilised or where the list/contract price is equivalent or lower than the PAS price.

#### Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3135), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Novartis Pharmaceuticals UK Ltd
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All Wales Medicines Strategy Group Final Appraisal Recommendation – 3516:  
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