Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 0719 – May 2019

Fingolimod (Gilenya®) 0.25 mg and 0.5 mg hard capsules

Limited submission by Novartis Pharmaceuticals UK Ltd

Recommendation of the All Wales Medicines Strategy Group

Fingolimod (Gilenya®) is recommended as an option for use within NHS Wales as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following groups of paediatric patients aged 10–17 years: patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy; 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.

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.
- It is the view of AWMSG that treatment for those aged under 16 years should be initiated and supervised by a paediatric neurologist.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2777), 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.

The All Wales Therapeutics and Toxicology Centre (AWTTC) reviewed this appraisal recommendation in December 2022. It will be reviewed again in three years.