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

This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland, or a list price that is equivalent or lower.

All Wales Medicines Strategy Group (AWMSG) decisions

The *All Wales Medicines Strategy Group* has advised (January 2017) that 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 only in patients with rapidly-evolving severe relapsing-remitting multiple sclerosis defined by 2 or more disabling relapses in 1 year and with 1 or more gadolinium-enhancing lesions on brain magnetic resonance imaging (MRI) or a significant increase in T2 lesion load compared with a previous recent MRI, only if the manufacturer provides fingolimod with the discount agreed as part of the patient access scheme or where the list price is equivalent or lower.

AWMSG No. 2777

The *All Wales Medicines Strategy Group* has advised (June 2019) that 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 patients aged 10 to 17 years with:

- highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy, **or**
- rapidly-evolving severe relapsing-remitting multiple sclerosis defined by two or more disabling relapses in one year, and with one 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.

NHS restrictions

NHS England Clinical Commissioning Policy NHS England (May 2014) has provided guidance on the use of fingolimod for the treatment of multiple sclerosis in England. An NHS England Clinical Commissioning Policy outlines the funding arrangements and the criteria for initiating and discontinuing this treatment option, see www.england.nhs.uk/commissioning/spec-services/npc-crg/group-d/d04/.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Capsule

- **Gilenya** (Novartis Pharmaceuticals UK Ltd) ▼
  Fingolimod (as Fingolimod hydrochloride)
  250 microgram Gilenya 0.25mg capsules | 28 capsule PoM £1,470.00
  Fingolimod (as Fingolimod hydrochloride)
  500 microgram Gilenya 0.5mg capsules | 7 capsule PoM £367.50 | 28 capsule PoM £1,470.00 DT = £1,470.00

Malignant disease

1 Antibody responsive malignancy

ANTINEOPLASTIC DRUGS › MONOCLONAL ANTIBODIES

Blinatumomab

26-Feb-2020

- **DRUG ACTION** The anti-lymphocyte monoclonal antibodies cause lysis of B lymphocytes.

- **INDICATIONS AND DOSE**

Relapsed or refractory Philadelphia chromosome-negative acute lymphoblastic leukaemia (initiated by a specialist)

- BY CONTINUOUS INTRAVENOUS INFUSION
- Child 1–17 years: (consult product literature)

- **CAUTIONS** Aphasia · brain injuries (severe) · cerebellar disease · dementia · elderly—limited information available · epilepsy · paresis · Parkinson's disease · patients may need pre-medication to minimise adverse reactions · psychosis · seizure · severe hepatic impairment · severe renal impairment · stroke

CAUTIONS, FURTHER INFORMATION

- **Pre-medication** Manufacturer advises pre-medication with a corticosteroid and an anti-pyretic—consult product literature.
- **Neurological events** There is potentially a higher risk of neurological events in patients with clinically relevant CNS pathology—manufacturer advises caution.

- **INTERACTIONS** → Appendix 1: monoclonal antibodies
- **SIDE-EFFECTS**
- **Common or very common** Abdominal pain · anaemia · aphasia · appetite decreased · arthralgia · chest pain · chills · cognitive disorder · confusion · constipation · cough · decreased leucocytes · diarrhoea · dizziness · dyspnoea · electrolyte imbalance · encephalopathy · facial swelling · fatigue · fever · flushing · headache · hyperglycaemia · hypersensitivity · hypertension · hypoalbuminaemia · hypotension · immune disorder · increased risk of infection · infusion related reaction · insomnia · leucocytosis · memory loss · nausea · neutropenia · oedema · pain · paraesthesia · rash · respiratory disorders · seizure · sepsis · tachycardia · thrombocytopenia · tremor · tumour lysis syndrome · vomiting · weight increased
- **Uncommon** Capillary leak syndrome · cranial nerve disorder · pancreatitis
- **Frequency not known** Device related infection · hypoxia · multi organ failure

SIDE-EFFECTS, FURTHER INFORMATION **Pancreatitis** Life-threatening or fatal cases of pancreatitis have been reported; manufacturer advises monitor for signs and symptoms of pancreatitis during treatment—temporary interruption or discontinuation may be required (consult product literature).

Cytokine release syndrome, infusion-reactions and tumour lysis syndrome Life-threatening (including fatal) cases of cytokine release syndrome and tumour lysis syndrome have been reported in patients taking blinatumomab. Manufacturer advises monitor signs and symptoms of cytokine release syndrome and infusion reactions during treatment; temporary interruption or discontinuation may be required—consult product literature.