Vigabatrin Shared Care Guideline

Introduction	**Uses/Licensed Indications:** • Treatment in combination with other anti-epileptic drugs for patients with resistant partial epilepsy with or without secondary generalisation; that is, where all other appropriate drug combinations have proved inadequate or have not been tolerated. • Monotherapy in the treatment of infantile spasms (West's syndrome). • Vigabatrin should be initiated by a specialist in epilepsy, a neurologist or a paediatric neurologist • Vigabatrin should not be initiated as monotherapy except in West's syndrome, where it remains as one of the first-line treatments. **Visual Field Defects and Tests** • Pooled data from prevalence surveys suggest that as many as 1/3 of patients receiving vigabatrin therapy have Visual Field Defects (VFDs). • Males may be at greater risk than females. • Most patients with perimetry-confirmed defects have not previously spontaneously noticed any symptoms, even in cases where a severe defect was observed in perimetry. • Available evidence suggests that the VFDs are irreversible even after discontinuation of vigabatrin. Therefore, vigabatrin should only be used after a careful assessment of the balance of benefits and risk compared with alternatives • If a visual field constriction is observed during follow-up, consideration should be given to gradual discontinuation of vigabatrin. If the decision to continue treatment is made, consideration should be given to more frequent follow-up (perimetry) in order to detect progression or sight threatening defects.
Dosing	**Epilepsy** With current antiepileptic therapy: • **ADULT** initially 1g daily in single or 2 divided doses then increased according to response in steps of 500 mg at weekly intervals; usual range 2–3g daily (max. 3g daily) • **CHILD** initially 40 mg/kg daily in single or 2 divided doses then adjusted according to body-weight 10–15kg, 0.5–1g daily; body-weight 15–30kg, 1–1.5g daily; body-weight 30–50kg, 1.5–3g daily; body-weight over 50kg, 2–3g daily. **Infantile spasms (West's syndrome)** • Monotherapy, 50 mg/kg daily, adjusted according to response over 7 days; up to 150mg/kg daily used with good tolerability.

Monitoring	**Adults** • Patients should have their visual fields assessed prior to treatment with vigabatrin and every 6 months while taking vigabatrin. The ophthalmology department at the RVI provides a vigabatrin visual field service with automatic recall every 6 months. Checking attendance for visual field checks and enquiry about visual symptoms should be a part of the annual primary care review of all patients taking vigabatrin. • Patients with learning difficulties may be unable to cooperate with visual field tests. A risk / benefit assessment should be made for each individual. • There is no need of regular visual field monitoring, after discontinuation of Vigabatrin. **Children** • Screening for visual field deficits is not possible much below the cognitive age of 9 years. Children with epilepsy should be under regular review by a paediatrician with expertise in epilepsy and where necessary a paediatric neurologist. These specialists should arrange visual screening for children taking vigabatrin at the appropriate time. • When visual field testing is feasible, it should be carried out every 6 months, whilst taking Vigabatrin. • If a child has been exposed to Vigabatrin at an age where they could not comply with testing and they then mature sufficiently to be tested, testing of visual fields would be advisable, whether they are still taking it or not, to establish any unwanted visual effects.
Specialist Responsibilities	• Initiation and provision of treatment with vigabatrin until patient is stabilised on the optimal dose. • Discussion with the patient/carer regarding the benefits, side effects and risks of treatment including the need for regular visual field monitoring. • To make appropriate arrangements for 6 monthly visual field checks or where these are not practical, alternative arrangements for visual screening/ monitoring. • Obtaining agreement of GP to participate in shared-care arrangement for vigabatrin therapy. • Regular follow up of the patient and subsequent adjustment of anti-epileptic therapy, as appropriate - if the patient is seizure-free on vigabatrin and the GP has agreed to supervise regular visual field checks, the patient will not need to be seen regularly by the hospital specialist team. • Prompt communication with the GP regarding the patient's progress, any reassessment and changes in treatment. • Provide additional information and advice to the GP on actions he/she may need to take e.g. on dosage adjustment, other changes in therapy and management of adverse effects, as required.
GP Responsibilities	• Reply to request for shared care as soon as practical (within 28 days). • Prescribe vigabatrin in accordance with the specialist's recommendations. Adjust the dosage of vigabatrin and if appropriate other therapy on the advice of the specialist. • Stop treatment on advice of, or in consultation with, a specialist - treatmentshould be withdrawn gradually. • As part of the annual primary care review of all patients with epilepsy: to enquire about visual symptoms and ensure that

	the patient has attended thehospital eye department for planned visual field checks. • To seek advice from the specialist immediately if a visual field defect isdetected. • To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment. • Referral to a specialist in the event of unsatisfactory control of the patient's epilepsy • Report adverse events to specialist and CSM.
Adverse Effects	**Common or very common** • Abdominal pain; alopecia; anaemia; anxiety; arthralgia; behaviour abnormal; concentration impaired; depression; dizziness; drowsiness; eye disorders; fatigue; headache; insomnia; memory loss; mood altered; nausea; oedema; paraesthesia; speech disorder; thinking abnormal; tremor; vision disorders; vomiting; weight increased **Uncommon** • Movement disorders; psychotic disorder; seizure (patients with myoclonic seizures at greater risk); skin reactions **Rare or very rare** • Angioedema; encephalopathy; hallucination; hepatitis; optic neuritis **Frequency not known** Intramyelinic oedema (particularly in infants); movement disorder (in infantile spasms) (in children); muscle tone increased
Precautions, Contraindications	• Hypersensitivity to vigabatrin or to any excipient in the medicinal product. • Any pre-existing significant visual field defect. • Vigabatrin should not be used concomitantly with other retinotoxic drugs. • Renal impairment (eGFR < 60ml/min), elderly – monitor closely for undesirable effects such as sedation and confusion. • Avoid sudden withdrawal (taper off over 2–4 weeks); history of psychosis, depression or behavioural problems; pregnancy and breast-feeding; absence seizures (may be exacerbated).
Common Drug Interactions	• Anticonvulsant effect of vigabatrin may be reduced by antidepressants (tricyclics, SSRIs and MAOIs) and antimalarials (chloroquine, hydroxychloroquine and mefloquine). • Use of vigabatrin may gradually lower plasma levels of phenytoin (by 16-33%), but this is not normally clinically important.
Communication/Contact Details	• NUTH Adult Epilepsy team 0191 2823995 • NUTH Paediatric Neurology 0191 282 1385

This information is not inclusive of all prescribing information and potential adverse effects.
Please refer to full prescribing data in the SPC or the BNF

Private and Confidential

Vigabatrin - Shared Care Request/Confirmation

- Specialist Prescriber to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 days
- A copy of the full shared care guideline can be viewed at www.northoftyneapc.nhs.uk

Specialist Prescriber				
Department				
Hospital				
Telephone				
Patient details (use hospital label if preferred)				
Name				
Address				
Postcode				
NHS or Hosp reg no		**Male / Female** Female	**DoB**	

Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement					
Drug Information – Vigabatrin					
Formulation		**Dose**		**Frequency**	
Indication –					
Other information (if appropriate) test					
Signed (Specialist Prescriber)		**Name (Print)**		**Date**	

To be completed by GP				**Please tick one box**	
I ACCEPT the proposed shared care arrangement for this patient					
I ACCEPT the proposed shared care arrangement with the caveats below					
I DO NOT ACCEPT the proposed shared care arrangement for this patient					
My caveats/reason(s) for not accepting include:					
test					
Signed		**Name (print)**		**Date**	

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP