THE SOUTH YORKSHIRE & BASSETLAW

Shared Care Guideline

For

The Management of Epilepsies in Children

Shared care guideline developed by:
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NHS Bassetlaw Clinical Commissioning Group
NHS Doncaster Clinical Commissioning Group
NHS Barnsley Clinical Commissioning Group Putting Barnsley People First
NHS Sheffield Clinical Commissioning Group
NHS Rotherham Clinical Commissioning Group
Sheffield Children's NHS Foundation Trust

This is guidance on the management of a condition not a commissioning arrangement

The Management of Epilepsy in Children

Statement of Purpose

This shared care guideline (SCG) has been written to enable the continuation of care by primary care clinicians of patients initiated on antiepileptic medication by the paediatric neurologists and/or the specialist epilepsy nurses at Sheffield Children's NHS Foundation Trust. Primary care will only be requested to take over prescribing of antiepileptic medication within its licensed indication unless specifically detailed otherwise in writing by the neurology team.

Responsibilities of consultant clinician

- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent. This is particularly important for unlicensed products or preparations being used off-label.
- To initiate anti-epileptic medication in appropriate patients
- To monitor seizure control by telephone assessment and/or clinic assessment with epilepsy nurse specialists/consultant neurologists
- To prescribe the first month's supply or until patient stable
- To contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care guideline.
- To advise the GP regarding continuation of treatment, including the length of treatment and any monitoring required.
- To monitor growth, seizure control and side effects and advise GP of any dose changes and monitor response.
- To discuss any concerns with the GP regarding the patient's therapy
- To prescribe valproate in line with MHRA advice:
  Valproate should not be prescribed to female children, female adolescents, women of childbearing potential or pregnant women unless other treatments are ineffective or not tolerated. Valproate is contraindicated in women and girls of childbearing potential unless there is a Pregnancy Prevention Programme in place. These conditions are also applicable to female patients who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy. In pregnancy, valproate must only be used for epilepsy if there is no suitable alternative treatment.
  Pregnancy prevention programme (Prevent) - If valproate is being used in a female of child bearing potential, ensure: they (or their carer) is made aware and understand the risks;
    - Are supplied with relevant literature; and signs a Risk Acknowledgement Form.
    - Ensure they are on highly effective contraception (if necessary)
    - Ensure all females of childbearing potential on valproate are seen at least annually to re-valuate treatment, contraception (if necessary), discuss risks and sign an updated Risk Acknowledgement Form.
- The patient to remain under the consultants care whilst ever the patient is being prescribed anti-epileptic medication

Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- To agree to prescribe for patients in line with the shared care agreement
- To report any adverse reaction to the MHRA and the referring consultant
- To continue to prescribe for the patient as advised by the consultant

- To undertake monitoring as per shared care guideline
- For patients taking valproate – Ensure all females who are of childbearing potential have been reviewed by a specialist in the last year and are on highly effective contraception. (Methods of contraception considered 'highly effective' in this context include the long-acting reversible contraceptives (LARC): copper intrauterine device (Cu-IUD), levonorgestrel intrauterine system (LNG-IUS) and progestogen-only implant (IMP); and male and female sterilisation. These all have a failure rate of less than 1% with typical use. See guidance from FSRH for more information on user-independent methods and failure rates).
  Further details on the responsibilities of the GP are given in the Guide for Healthcare Professionals.
- To inform the consultant if the patient discontinues treatment for any reason
- To seek the advice of the consultant if any concerns with the patient's therapy
- To conduct an annual face to face medication review or more frequent if required
- In the event that the GP is not able to prescribe, or where shared care is agreed but the consultant is still prescribing certain items e.g. Hospital only product; the GP will provide the consultant with full details of existing therapy promptly by fax on request.
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist Issued Drugs on Clinical Practice Systems

Responsibilities of Patients or Carers

- To attend hospital and GP clinic appointments and to bring monitoring booklet (if applicable). Failure to attend will potentially result in the medication being stopped.
- Present rapidly to the GP or specialist should their clinical condition significantly worsen.
- Report any suspected adverse effects to their specialist or GP whilst taking anti-epileptic medication.
- To read the drug information given to them, including, if relevant patient guide for valproate pregnancy prevention programme.
- To take anti-epileptic medication as prescribed
- Inform the specialist, GP or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.

Indication

Children with a diagnosis of epilepsy who have continuing uncontrolled seizures. This shared care guideline follows NICE Guidance CG137 The Epilepsies: the diagnosis and management of epilepsies in adults and children in primary and secondary care (Jan 2012 updated April 2018). Please refer to this guideline for further information.

At a consultant's discretion and where expected benefits exceed the risks, the dose may be increased beyond the maximum recommended in the BNFc if tolerated by the patient. The consultant will be responsible for discussing unlicensed use of these agents with patients and their carers.

Formulation switching of antiepileptics

Concerns about switching between different manufacturers' products of antiepileptic drugs (AEDs) have been raised by patients and prescribers. These include switching between branded original and generic products, and between different generic products of a particular drug.

Different AEDs vary considerably in their characteristics, which influence the risk of whether or not switching between different manufacturers' products of a particular drug may cause adverse effects or loss of seizure control.
Following a review of the available evidence, the UK Commission on Human Medicines (CHM) considered the characteristics of AEDs and advised that they could be classified into three categories, based on therapeutic index (a comparison of the amount of a therapeutic agent that causes the therapeutic effect to the amount that causes or toxicity), solubility and absorption, to help prescribers and patients decide whether it is necessary to keep using a supply of a specific manufacturer's product. See MHRA Drug Safety Update for details.

Category 1 – Phenytoin, carbamazepine, phenobarbital, primidone

For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product.

Category 2 – Valproate, lamotrigine, perampanel, retigabine, rufinamide, clobazam, clonazepam, oxcarbazepine, eslicarbazepine, zonisamide, topiramate

For these drugs the need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with patient and/or carer taking into account factors such as seizure frequency and treatment history. Take into account patient/carer-related factors such as their negative perceptions about alternative products and/or other issues related to the patient.

Category 3 - Levetiracetam, lacosamide, tiagabine, gabapentin, pregabalin, ethosuximide, vigabatrin, brivaracetam

For these drugs it is usually unnecessary to ensure that patients are maintained on a specific manufacturer's product unless there are specific concerns such as patient anxiety, and risk of confusion or dosing errors. Take into account patient/carer-related factors such as their negative perceptions about alternative products and/or other issues related to the patient should also be taken into account.

Dosage

For information regarding dosing, side-effects, contra-indications, precautions, drug interactions and monitoring, please refer to the BNFc or manufacturer's Summary of Product Characteristics available from www.emc.medicines.org.uk

Information for parents, carers and patients on the individual drugs included can be found at - https://www.medicinesforchildren.org.uk/

Drug	Licensing information	Off label use	Other information
Brivaracetam	Over 16 years - Adjunctive therapy of partial-onset seizures with or without secondary generalisation		
Carbamazepine	Children. Monotherapy for focal seizures and tonic-clonic seizures secondary to a focal discharge.		When possible tablet formulation is preferable to liquid.

Drug	Licensing information	Off label use	Other information
Clobazam	6 years and over - As adjunctive therapy	Children 1 months to 6 years in exceptional circumstances. Monotherapy under specialist supervision for catamenial seizures.	
Clonazepam	Over 1 month of age - All types of epilepsy over 1 month of age		
Ethosuximide	Children. Monotherapy for absence seizures, atypical absences (adjunct) and myoclonic seizures.		
Gabapentin	Children over 6 years - Adjunctive treatment of focal seizures with or without secondary generalisation. Can be used as monotherapy in children aged over 12 years.		
Lacosamide	Children aged over 4 years Monotherapy and adjunctive treatment of focal seizures with or without secondary generalisation.		
Lamotrigine	2- 12 years -Adjunctive treatment of partial seizures and generalised seizures, including tonic clonic seizures and the seizures associated with Lennox Gastaut syndrome. Monotherapy of typical absence seizures. 13 years and over; Adjunctive or monotherapy treatment of partial seizures and generalised seizures, including tonic clonic seizures. Seizures associated with Lennox Gastaut syndrome.		

Drug	Licensing information	Off label use	Other information
Levetiracetam	From 1 month - Adjunctive treatment of focal seizures with or without secondary generalisation. Aged over 16 years - Monotherapy of focal seizures with or without secondary generalisation. From 12 years - Adjunctive therapy of myoclonic seizures and tonic-clonic seizures		
Oxcarbazepine	Children aged over 6 years Monotherapy and adjunctive treatment for focal seizures with or without secondary generalisation.		
Perampanel	Children aged over 12 years - Adjunctive treatment of focal onset seizures with or without secondary generalisation and primary generalised tonic-clonic seizures.		
Phenytoin	All forms except for absence seizures in childhood (age not specified by manufacturer). Licensed for status epilepticus or acute symptomatic seizures following neurosurgery, head injury.		
Phenobarital	Neonate onwards - All forms of epilepsy except for typical absence seizures		
Rufinamide	Patients over 4 years - Adjunctive treatment for Lennox Gastaut syndrome.		

Drug	Licensing information	Off label use	Other information
Sodium valproate	All ages - All forms of epilepsy.		***See additional safety information below around use in girls, female adolescents and women of child bearing age.**
**Stiripentol	Children over 3 years - Adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet Syndrome).		BNFc and SPC recommends 6 monthly FBC and LFTs, however based on expert opinion at SCH, routine monitoring not generally done unless clinically needed. The consultant should discuss and agree this with the patient / carer on a case by case basis
Tiagabine	Children over 12 years - Adjunctive treatment for focal seizures with or without secondary generalisation.		
Topiramate	Children over 6 years - Monotherapy of generalised tonic-clonic or focal seizures with or without secondary generalisation Children 2 years and over - Adjunctive therapy with partial onset seizures with or without secondary generalization or primary generalized tonic-clonic seizures and for the treatment of seizures associated with Lennox-Gastaut syndrome.		
Vigabatrin	Adjunctive therapy for focal epilepsy with or without secondary generalisation in which other combinations are unsuccessful or not tolerated. Monotherapy for the management of infantile spasms		

	(West's syndrome).		
Drug	**Licensing information**	**Off label use**	**Other information**
Zonisamide	Aged 6 years and over - Adjunct therapy for refractory focal seizures with or without secondary generalisation.		
Rectal diazepam	Children over 1 year - Rescue medication for prolonged seizures / clusters of seizures.		
Buccal midazolam	Buccolam® 5mg/ml Licensed for children 3 months and over. Rescue medication for prolonged seizures / clusters of seizures.		See additional safety advice regarding Buccolam® - Link
**Rectal paraldehyde In equal parts olive oil		Rescue medication for status epilepticus	Available from Stockport Pharmaceuticals

****Subject to Traffic Light Drug status in receiving CCG

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See Guide for Healthcare Professionals (Valproate pregnancy prevention programme) for more information - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708850/123683_Valproate_HCP_Booklet_DR15.pdf

Monitoring

Regular blood test monitoring in children and young people is not recommended as routine, and should be done only if clinically indicated and recommended by the specialist. Children will be regularly reviewed in the specialist epilepsy consultant led clinics and in epilepsy nurse review clinics.

Medications will be commenced or withdrawn on the written instructions of the consultant neurologists or epilepsy nurse specialists.
Use the Yellow Card System to report adverse drug reactions directly to the MHRA. Yellow Cards and guidance on its use are available at the back of the BNF. Alternatively report online at www.mhra.gov.uk/yellowcard

Re-Referral guidelines

- If the patient discontinues treatment for any reason
- If any concerns with the patient's therapy
- If the patients clinical condition significantly worsens.

Financial implications

Reduced outpatient appointments
Reduced emergency and hospital admissions

Support, education and information

Epilepsy Nurse Advice Line: 0114 2717620 Monday- Friday 9am-5pm

The on-call paediatric neurologist can be contacted via Sheffield Children's NHS Foundation Trust switchboard 0114 2717000

www.medicinesforchildren.org.uk

www.emc.medicines.org.uk

References

1. NICE CG137. Jan 2012 (updated April 2018)

   https://www.nice.org.uk/guidance/cg137

2. MHRA. Antiepileptic drugs: updated advice on switching between different manufacturers' products. Nov 2017 https://www.gov.uk/drug-safety-update/antiepileptic-drugs-new-advice-on-switching-between-different-manufacturers-products-for-a-particular-drug

3. Medicines related to valproate: risk of abnormal pregnancy outcomes. Jan 2015. https://www.gov.uk/drug-safety-update/medicines-related-to-valproate-risk-of-abnormal-pregnancy-outcomes and update 2018 - https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met

4. https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-pregnancy-prevention-programme-materials-online

5. Electronic Medicines Compendium - https://www.medicines.org.uk/emc/

6. BNFc https://www.medicinescomplete.com/#/browse/bnfc

(Template letter to GP)

Dear Doctor

RE: …….. DOB: …… NHS No. ……..

Address: …….

Your patient is being started on treatment with (enter Medication).

This treatment can be prescribed by GPs under the Traffic Light System under the "shared care" arrangements. This shared care guideline has been approved by the Sheffield, Rotherham, Barnsley and Doncaster and Bassetlaw Area Prescribing Committees /Groups.

http://www.intranet.sheffieldccg.nhs.uk/medicines-prescribing/shared-care-protocols.htm

We have chosen to use …….. ……because …….

As part of shared care arrangements please can you monitor xxxxxxx(e.g. FBC, eGFR), adherence, response and side effects to therapy every XX months. Will you also please undertake to prescribe for your patient?

Please acknowledge you are happy to take on shared care by completing and returning the slip below to above address or by faxing to …….

Do not hesitate to contact us if you have any concerns.

Yours sincerely

Clinician's Name

Clinician's Title

IMPORTANT REMINDER

The prescribing doctor is responsible for monitoring the patient on the medication being prescribed

_____*please tear here, return to address or fax* _____

RE: …… DOB: …… NHS:……..

Address: …….

☐ I AGREE to take on shared care of this patient

☐ I DO NOT AGREE to take on shared care of this patient

Signed …… GP Practice…… Date……

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