BNSSG Paediatric Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Levetiracetam
Amber ***three months***	
Indication	1. Monotherapy of focal seizures with or without secondary generalisation 2. Adjunctive therapy of focal seizures with or without secondary generalisation 3. Adjunctive therapy of myoclonic seizures and tonic-clonic seizures
Speciality / Department	Paediatrics
Trust(s)	University Hospitals Bristol NHS Foundation Trust

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed for this age group and any relevant dosing information)*	For Child 1–5 months Initially 7 mg/kg once daily, then increased in steps of up to 7 mg/kg twice daily (max. per dose 21 mg/kg twice daily), dose to be increased every 2 weeks. Child >6 months – 18 years and body weight <50kg: Initially 10 mg/kg once daily, then increased in steps of up to 10 mg/kg twice daily (max. per dose 30 mg/kg twice daily), dose to be increased every 2 weeks. Dosage can be increased quicker if child is an inpatient, or at the discretion of the neurology consultant. Child 12 – 18 years and body weight >50kg: Initially 250mg twice daily, then increased in steps of 500mg twice daily (max. per dose 1.5g twice daily), dose to be increased every 2-4 weeks. Dosage can be increased quicker if child is an inpatient, or at the discretion of the neurology consultant.
Route and preferred formulation *(Please indicate licensed or unlicensed preparation)*	Oral: liquid, tablets and granules Granules not licensed for use in children under 6 years, for initial treatment in children with body-weight less than 25kg, or for the administration of doses below 250mg.
Duration of treatment	Long term Treatment should be reviewed, and most often would be stopped, if two years have elapsed without any witnessed clinical seizures. This is the responsibility of secondary care. If patient becomes pregnant or wishes to become pregnant, refer to secondary care for review of treatment.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist)

Baseline tests to be done by secondary care

Check urine and electrolytes (U&E) and liver function test (LFT) if concern of renal or hepatic impairment

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results. If the drug is dosed by weight please also indicate intended frequency of weight monitoring/dose adjustment)*

Test	Frequency	Who by	Action/management
Monitor U+Es if concerns about renal impairment.	4-6 weeks after initiation. In paediatric practice we would generally then do every 12 months	Secondary care	Specialist to manage if abnormal
Vitamin D levels	Every 12 months	Secondary care	Levetiracetam can alter vitamin D metabolism. Secondary care to check levels 12 monthly and consider supplementation as necessary- GP may be asked to prescribe supplementation as per local guidelines.

Frequency of ongoing follow up by secondary care *(Please indicate how often child will continue to be seen by secondary care i.e. at least every 6 months)*	At least every 12 months

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNFc or SPC.

Side effects and management

Side effect	Frequency/severity	Action/management
Behaviour symptoms, including agitation, hostility, oppositional behaviour, anxiety, aggression, emotional lability, depression	Common, more commonly seen at the start of treatment.	Slower titration of medication may be necessary, however if still experiencing problems after two weeks refer to specialist.
Abdominal pain, diarrhoea, dyspepsia, vomiting, nausea	Common, more commonly seen at the start of treatment.	Slower titration of medication may be necessary, side effects should subside, however if treatment needs to be discontinued refer to specialist.

	<table><tr><td>Rash</td><td>Common, more commonly seen at the start of treatment.</td><td>Slower titration of medication may be necessary, side effects should subside. Contact specialist if they do not.</td></tr><tr><td>Toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme</td><td>Rare</td><td>Stop treatment and refer to specialist.</td></tr></table>
Referral back to specialist	If not tolerating side effects and medication stopped.

Section 5: Other Issues
(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent and the action for GP to take (For full list please see BNFc or SPC)

Issues	**Renal impairment:** If creatinine clearance is <80ml/minute dosage should be reduced, secondary care to manage. **Hepatic impairment:** If patient has severe hepatic impairment and creatinine clearance is <60ml/min, the dose should be halved. Secondary care to manage. **Cautions** Suicide, suicide attempt, suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents (including levetiracetam). Therefore patients should be monitored for signs of depression and/or suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of depression and/or suicidal ideation or behaviour emerge. **Pregnancy** Levetiracetam is considered one of the safer anticonvulsants to use during pregnancy so contraception not essential. See MHRA: Antiepileptic drugs in pregnancy updated advice following comprehensive safety review. In the event a patient becomes pregnant whilst being prescribed levetiracetam, patients should be referred to the neurology consultant for review.
Reminder to ask patient about specific problems	When appropriate check type of contraceptive patient is using.

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

N/A

Section 7: Generic principles of shared care for SECONDARY CARE

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review in frequency specified in **section 3** and adjust dose for child's age/body weight as appropriate.
7. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
8. Stopping treatment where appropriate or providing advice on when to stop.
9. Reporting adverse events to the MHRA.
10. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Paediatric neurology consultant	University Hospitals Bristol	Via switchboard 0117 923 0000	Click here to enter details
Paediatric neurology registrar	University Hospitals Bristol	Via switchboard 0117 923 0000 bleep 6734	Click here to enter details

Section 10: Document Details

Date prepared	October 2018, revised 2021
Prepared by	Rebekah Rogers/Ceri Gaskell (Pharmacists) and Andrew Lux (Neurology consultant)
Date approved by JFG	June 2021
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Document Identification: Version	V1

Section 11: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

N/A

Section 12: References

Please list references

1. Paediatric Formulary Committee. (November 2018) British National Formulary for Children (BNFc) [online]. London: BMJ Group, Pharmaceutical Press and RCPCH Publicaions. Available from: http://www.medicinescomplete.com [Accessed 16 Nov. 18]
2. UCB Pharma Limited. (January 2017) Keppra 100mg/ml oral solution. Available from: https://www.medicines.org.uk/emc/product/2295/smpc [Accessed 16 Nov. 18]
3. University Hospitals Bristol (September 2018) Levetiracetam dosing guideline.
4. Patsalos P.N and Bourgeois B.F.D. (2014) The Epilepsy Prescriber's Guide to Antiepileptic Drugs. 2nd ed. Cambridge University Press, Cambridge.