BNSSG Paediatric Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Clobazam
Amber ***three months***	
Indication	Adjunctive therapy for epilepsy, cluster seizures

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	**Child 1 month-5 years (unlicensed):** Initially 125 micrograms/kg twice daily, dose to be increased if necessary every 5 days, maintenance 250 micrograms/kg twice daily (max. per dose 500 micrograms/kg twice daily); maximum 30 mg per day (in at least two divided doses). **Child 6-17 years:** Initially 5 mg daily, dose to be increased if necessary at intervals of 5 days, maintenance 0.3–1 mg/kg daily, daily doses of up to 30 mg may be given as a single dose at bedtime, higher doses should be divided; maximum 60 mg per day (in at least two divided doses). Dose adjustment as per age/body weight will be undertaken by secondary care.
Route and formulation	Oral: Tablets and liquid (Licensed). If patient requires liquid, prescribe **10mg/5mL** strength liquid within BNSSG to reduce risk of errors with changes in formulation strength. **Doses prescribed should specify both mass (mg)** and **volume (mls)** e.g. 'Take 5mg (2.5ml)'. If GP Practices are asked to continue prescribing for children from clinical letters/discharges, the correct strength and dosage should be confirmed with the prescriber or specialist team if there is any risk of ambiguity.
Duration of treatment	Long term, or short-term adjunct (typically between 5 and 14 days) for seizure exacerbation or to cover changes in regular antiepileptic medications. 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.

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 - where appropriate			
N/A			
Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*			
Test	Frequency	Who by	Action/management
N/A			

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 BNF or SPC.

Side effects and management	Side effect	Frequency/severity	Action/management
	Drowsiness	Common	More common at beginning of treatment. May reduce with continued treatment or decreased dose. Monitor for respiratory depression if excessive drowsiness.
	Aggression/irritability	Common	Refer to specialist for review of treatment. Adjustment of dose (up or down) may be necessary
	Ataxia	Common	Refer to specialist for review of treatment.
Referral back to specialist	If maximum dose reached and hasn't achieved an effect, or not tolerating treatment. Secondary care will follow up at least every 12 months.		

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

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

Issues	**Drug Interactions** Clobazam can increase plasma levels of phenytoin, stiripentol and valproic acid. Phenytoin, phenobarbital, perampanel and carbamazepine can decrease clobazam levels. Voriconazole,

	fluconazole and omeprazole potentially increase exposure to clobazam. Caution use with other drugs that have CNS depressant effect due to additive effects. **Cautions, Contra-indications** Avoid abrupt withdrawal. Contraindicated in acute pulmonary insufficiency and respiratory depression, sleep apnoea and unstable myasthenia gravis. **Special Recommendations** Ensure that strength of formulation and dose in mg and mL is specified on all prescriptions and clinic letters to avoid prescribing errors. Local recommendation (BNSSG) to prescribe clobazam liquid only with the 10mg/5mL (2mg/mL) strength.
Reminder to ask patient about specific problems	N/A

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. May cause drowsiness.
2. If used on a long-term basis, do not stop medication immediately, may need to withdraw slowly
3. Ensure patient is aware that different strengths of the medicine are available and to be clear when stating dose in mg or mL. Local recommendation (BNSSG) to prescribe clobazam liquid only with the 10mg/5mL (2mg/mL) strength and for dose to be recorded in mg and ml

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

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 concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

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	UHBW	Via switchboard 0117 923 0000	Click here to enter details
Paediatric neurology registrar	UHBW	Via switchboard 0117 923 0000 bleep 6734	Click here to enter details
Paediatric neurology pharmacists	UHBW		paediatricneurologypharmacists@uhbw.nhs.uk

Section 10: Document Details

Date prepared	2024
Prepared by	Ceri Gaskell (Pharmacist) and Andrew Lux (Consultant)
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Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. N/A

Section 12: References

Please list references

1. Paediatric Formulary Committee. (September 2023) British National Formulary for Children (BNFc) [online]. London: BMJ Group, Pharmaceutical Press and RCPCH Publications. Available from: https://bnfc.nice.org.uk [Accessed 13 November 2023].
2. 2. Martindale Pharma. (September 2022). Tapclob 10mg/5ml oral suspension. Available from: https://www.medicines.org.uk/emc/product/3010/smpc [Accessed 13 November 2023]