Royal Cornwall Hospitals NHS Trust

Policy Under Review

Please note that this policy is under review. It does, however, remain current Trust policy subject to any recent legislative changes, national policy instruction (NHS or Department of Health), or Trust Board decision. For guidance, please contact the Author/Owner.

Information Category	Detailed Information
Document Title:	Buccal Midazolam for the Treatment of Prolonged Seizures in Children Shared Care Guideline V3.0
This document replaces (exact title of previous version):	Buccal Midazolam for the Treatment of Prolonged Seizures in Children V2.2
Date Issued / Approved:	November 2022
Date Valid From:	November 2022
Date Valid To:	May 2026
Author / Owner:	Mike Wilcock, Head of Prescribing Support Unit / Pharmacy
Contact details:	01872 253548
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists
Suggested Keywords:	Midazolam
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee
Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming consultation and ratification:	Kevin Wright

Information Category	Detailed Information
Links to key external standards:	None
Related Documents:	No
Training Need Identified:	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
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Buccal Midazolam for the Treatment of Prolonged Seizures in Children Shared Care Guideline

V3.0

November 2022

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of buccal midazolam when used in the treatment of status epilepticus.

1.2. This shared care guideline sets out details for the sharing of care of children with epilepsy requiring treatment for prolonged seizures (> 5 minutes) in the community. These guidelines provide additional limited information necessary to aid in the treatment of these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant guidance and do not replace them.

1.3. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1. **Buccolam**

2.1.1. Buccolam is licensed for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents preparation from 3 months to < 18 years. It is given buccally to treat prolonged seizures lasting longer than 5 minutes Note that some patients may be advised on an individual basis to wait either slightly shorter or longer than 5 minutes. Buccal midazolam is frequently used in paediatrics as an alternative to rectal diazepam. It is widely used throughout the UK and is recommended in the SIGN and NICE guidelines for treatment of epilepsy. Further prescribing information can be found in the BNF for Children.

2.1.2. Epilepsy Specialist Nurse Association has available best practice guidance for training professional carers in the administration of Buccal (Oromucosal) Midazolam for the treatment of prolonged and / or clusters of epileptic seizures in the community.

2.1.3. There is a CFT Policy for use of oral mucosal midazolam for the minority of ADULTS who require emergency treatment for seizures to prevent status epilepticus which can result in brain injury or death. This CFT policy advises brand prescribing of Epistatus or Buccolam.

2.2. Preparations and Dosage

2.2.1. Buccolam is available as a 5mg/mL solution and. It is available as pre-filled oral syringes in ready to use doses of 2.5mg, 5mg, 7.5mg and 10mg.

2.2.2. The correct prefilled syringe size for the dose required must be prescribed.

2.2.3. Buccolam remains the preferred brand of buccal midazolam pre-filled syringes. It is important to note that the other brand of pre-filled syringes (Epistatus) is occasionally used BUT Epistatus is a different concentration (10mg/ml). If changing from Epistatus to Buccolam it is imperative that patient, parent(s) and carer(s) understand the change in concentration.

2.2.4. Buccolam is dosed by age as described in the table below. Some patients may be advised by their secondary care clinician to consider the use of a repeat dose.

Age range	Dose	Label colour
3 to 6 months hospital setting	2.5mg	Yellow
> 6 months to < 1 year	2.5mg	Yellow
1 year to < 5 years	5 mg	Blue
5 years to < 10 years	7.5 mg	Purple
10 years to < 18 years	10 mg	Orange

2.3. Administration

SEE PATIENT INFORMATION LEAFLET

The oral syringe is removed from the packaging and the cap removed. By slowly pushing down the plunger, approximately half of the dose is placed between the lower gums and the cheek on one side of the mouth and remainder of the dose given in the same way on the other side of the mouth. Full instructions are given in the patient information leaflet found inside the carton, and the consultant will provide individualised administration guidelines for the family which will also be available to the GP.

2.4. Contraindications and Precautions

2.4.1. Buccal midazolam is contraindicated in cases of:

- Known hypersensitivity to midazolam or any of the excipients
- Myasthenia gravis
- Severe respiratory insufficiency
- Sleep apnoea syndrome
- In patients with severe hepatic impairment

2.4.2. Insufficient data are available on midazolam to assess its safety during pregnancy but it may be used during pregnancy if clearly necessary.

2.4.3. Although no dose adjustment is required, Buccolam should be used with caution in patients with chronic renal failure as elimination of midazolam may be delayed and the effects prolonged.

2.5. Monitoring

Although no routine monitoring is necessary, if patients are being changed from one brand of buccal midazolam to a different brand it is imperative that patient, parent(s) and carer(s) understand the change in strength. The ongoing need for prescribing should be discussed with the patients regularly by the medical team (consultant paediatrician) and specialist epilepsy nursing teams. Discussions and outcomes about this should be communicated to the GP.

2.6. Side Effects

The most common side effect is drowsiness, which may last for several hours after administration. Agitation, restlessness and disorientation have been reported, although these side effects are rare. Respiratory depression may occur at high doses.

2.7. Common / significant drug interactions

2.7.1. Drugs such as erythromycin, other macrolides, azole antifungals and cimetidine inhibit the metabolism of midazolam and can prolong the sedative side effect.

2.7.2. Cimetidine, ranitidine and omeprazole have been shown to reduce the clearance of midazolam and other benzodiazepines and may potentiate their actions.

2.8. Areas of Responsibility for the Sharing of Care

2.8.1. These are suggested ways in which the responsibilities for the management of children with epilepsy requiring treatment with buccal midazolam for prolonged seizures (> 5 minutes) in the community can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient.

The intention to share care should be explained to the patient and be accepted by them.

2.8.2. **In the NHS E guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.**

2.8.3. **Specialist:**

- Make any necessary diagnoses and communicate these to the GP and other professionals involved in the patient's care.
- Discuss the treatment options with the patient, his/her parent(s) and carer(s). Patient information leaflet is found inside the product's box.
- Ensure the parent/carer is trained and understand when and how to give the medication.
- Request the GP to take over prescribing in a clear letter, which should include full clinical details using the suggested wording template (Appendix 3). Where patients/carers have been advised to consider use of a repeat dose of Buccolam, this should be explicitly stated in the letter to the GP.
- Ensure the parents and the carer(s) are trained in the administration of Buccolam.
- Ensure the patient is provided with at least four doses (one pack) from the date the GP accepts the request to continue prescribing.
- Ensure the patient/parent/carer is fully aware of the need to obtain a prescription from their GP within 2 weeks and to take it immediately to their chosen community pharmacy so that arrangements can be made to obtain stocks.
- Continuing need for prescription to be reviewed at least annually.
- Communicate any changes, recommendations, or other important information to the GP.
- Provide advice to the GP if they have clinical queries relating to the underlying condition or use of Buccolam.
- Take back care of the patient should the GP feel unable to continue to manage the prescribing of Buccolam

2.8.4. **General Practitioner:**

- To respond to the shared care request from the consultant in writing without undue delay.
- Accept the request to continue prescribing of Buccolam within the boundaries of this shared care protocol, for which prescribing responsibilities will commence 4 weeks from the date of reply. Please note that Buccolam is a controlled drug and the usual prescribing regulations apply.
- Prescribe appropriate quantities for the patient on a regular basis.
- Carry out further dose titration according to the patient's age, or discontinue the medication, when necessary or requested.
- Communicate any problems to the Specialist looking after the patient.
- Only ask the Specialist to take back the prescribing should unmanageable problems develop and allow an adequate notice period (4 weeks is a suggested minimum).

2.8.5. **Patient / parent / guardian / carer:**

- Agree to request prescriptions from the GP in good time and obtain the first GP prescription within 2 weeks of being informed that shared care will be in operation.
- Report any concerns or adverse effects to the GP, Specialist or Pharmacist.
- Patient information leaflet can be found inside the product's box.

2.8.6. **Information for Community Pharmacies and Dispensing GPs**

- Currently the preparation of buccal midazolam of choice is Buccolam pre-filled syringe.

BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice)
Lead	Head of Prescribing Support Unit
Tool	Adherence to guidelines will be monitored as part of the ongoing audit process on a Word or Excel template specific to the topic.
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee
Acting on recommendations and Lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

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Date Issued/Approved:	November 2022
Date Valid From:	November 2022
Date Valid To:	November 2025
Directorate / Department responsible (author/owner):	Mike Wilcock, Head of Prescribing Support Unit / Pharmacy
Contact details:	01872 253548
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists
Suggested Keywords:	Midazolam
Target Audience:	RCHT: Yes CFT: No CIOS ICB: No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	None
Related Documents:	No
Training Need Identified?	No

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
	V1.0	New guideline in this format	M Wilcock, Head of Prescribing Support Unit
Jan'17	V1.1	Minor amendments	M Wilcock, Head of Prescribing Support Unit
Nov 19	V2.0	New version in this format and placed on latest Trust template.	M Wilcock, Head of Prescribing Support Unit
March 2020	V2.1	Appendix 3 added following FRG approval - CHA4215 Shared Care Agreement Letter Consultant Request	Demi Louise Kent, Corporate Records Manager
Sept 2021	V2.2	Replacement of shared care agreement letter with suggested wording template instead	M Wilcock, Head of Prescribing Support Unit
Nov 2022	V3.0	New text under 2.1.2, 2.1.3 and 2.5	M Wilcock, Head of Prescribing Support Unit

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

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Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Buccal Midazolam for the Treatment of Prolonged Seizures in Children Shared Care Guideline V3.0
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow
Contact details:	01726 627953

Information Category	Detailed Information
1. **Policy Aim - Who is the Policy aimed at?** (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide information on prescribing of buccal midazolam to enable General Practitioners to take over prescribing responsibility from secondary care.
2. **Policy Objectives**	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area)
3. **Policy Intended Outcomes**	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. **How will you measure each outcome?**	Six monthly review
5. **Who is intended to benefit from the policy?**	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Cornwall Area Prescribing Committee
6c. What was the outcome of the consultation?	Agreed
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:**

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Suggested wording for Specialist communication re commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you are in agreement, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment.)

Baseline tests: (insert information)

Next review with this department: (insert date)

You will be sent a written summary within (XX) days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.