SHARED CARE GUIDELINE FOR BUCCAL MIDAZOLAM FOR THE TREATMENT OF PROLONGED SEIZURES IN CHILDREN

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.

2. The Guidance

2.1. See below for the Shared Care Guideline.

This shared care guideline sets out details for the sharing of care of epileptic children 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.

INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE

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

PREPARATIONS AND DOSAGE

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

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

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.

CONTRAINDICATIONS AND PRECAUTIONS

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

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

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.

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.

SIDE EFECTS

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.

COMMON/SIGNIFICANT DRUG INTERACTIONS

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

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

Request for other formats

Please ask if you would like to receive this leaflet in large print, braille, on CD or in any other languages. If you would like the leaflet in an alternative format please contact the NHS Kernow communications Team at communications@kernowccg.nhs.uk or call 01726 627800

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of epileptic children 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.

In its guidelines on responsibility for prescribing (circular EL(91)127) between hospitals and GPs, the DH has advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

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), to include explanation of the unlicensed nature of Buccolam in adults, obtaining appropriate consent to treatment and to share care with the GP. Patient information leaflet is found inside the product's box.
- Ensure the parent/carer 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 and document that the unlicensed nature of Buccolam in adults has been discussed with the patient/parent/carer and consent obtained. 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 (two packs) **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.

General Practitioner:

- If the GP agrees to shared care he/she will notify the consultant in writing without undue delay.
- Ensure that the patient, their parent(s) and carer(s) has understood and consented to the unlicensed use of Buccolam in adults. A patient information leaflet is found inside the product's box.
- 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).

Patient: and parent / carer responsibilities

- 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.

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

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	No specific tool
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Medicines Practice Committee
Acting on recommendations and Lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Relevant Clinical Staff

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement.

4.2. Equality Impact Assessment

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

Appendix 1. Governance Information

Document Title	Shared Care Guideline for buccal midazolam for the treatment of prolonged seizures in children					
Date Issued/Approved:	12 February 2014					
Date Valid From:	12 February 2014					
Date Valid To:	1 February 2017					
Directorate / Department responsible (author/owner):	M Wilcock, Head of Prescribing Support Unit, Pharmacy Department, RCHT					
Contact details:	01872 253548					
Brief summary of contents	Some clinical issues and details of prescribing responsibilities for GP and specialists					
Suggested Keywords:	Shared care					
Target Audience	RCHT	CCG	CFT			
	✓	✓	✓			
Executive Director responsible for Policy:	Medical Director					
Date revised:	20 November 2013					
This document replaces (exact title of previous version):	Buccal midazolam for the treatment of prolonged seizures in children					
Approval route (names of committees)/consultation:	Cornwall Area Prescribing Committee					
Divisional Manager confirming approval processes	M Wilcock					
Name and Post Title of additional signatories	Not Required					
Signature of Executive Director giving approval	{Original Copy Signed}					
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only			
Document Library Folder/Sub Folder	Clinical / Pharmacy					
Links to key external standards	None					
Related Documents:	None					

Training Need Identified?	No

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
	V1.0	New guideline in this format	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

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2.Initial Equality Impact Assessment Screening Form

Name of service, strategy, policy or project (hereafter referred to as *policy)* to be assessed: Shared Care Guideline for the treatment of Attention Deficit Hyperactivity Disorder in children under 18 years of age	
Directorate and service area: Pharmacy	Is this a new or existing Procedure? Existing
Name of individual completing assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow	Telephone:01726 627953
1. Policy Aim*	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.
5. How will you measure the outcome?	If the guideline is not well received, publicised and adopted, then some GPs may not enter into shared care arrangements.
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.
6a. Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b. If yes, have these groups been consulted? c. Please list any groups who have been consulted about this procedure.	No Cornwall & IoS Area Prescribing Committee

7. The Impact Please complete the following table.			
Are there concerns that the policy **could** have differential impact on:			
Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		✓	
Sex (male, female, trans-gender / gender reassignment)		✓	

Race / Ethnic communities /groups		✓	
Disability - learning disability, physical disability, sensory impairment and mental health problems		✓	
Religion / other beliefs		✓	
Marriage and civil partnership		✓	
Pregnancy and maternity		✓	
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		✓	

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**	**No** ✓

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director	Date of completion and submission

Names and signatures of members carrying out the Screening Assessment	1. Dan Thomas 2. Mike Wilcock	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust's web site.

Signed _____ Dan Thomas and Mike Wilcock _____

Date _____ January 2014 _____