BSW APC: BaNES, Swindon & Wiltshire (BSW) CCG, Avon & Wiltshire Mental Health Partnership NHS Trust (AWP), Royal United Hospitals Bath NHS Foundation Trust, Great Western Hospitals NHS Foundation Trust, Salisbury NHS Foundation Trust, Virgin Care, Swindon Community Health Services, Wiltshire Health & Care

SHARED CARE AGREEMENT

Use of Oromucosal Midazolam Hydrochloride (Buccolam ® 10mg in 2ml) as an intervention for prolonged seizures and prevention of Status Epileptics in children from 3 months to under 18 years old

Amber TLS – 1 Month

Principles of Shared Care

Shared care agreements (SCAs) provide a framework for the seamless transfer of care from a hospital or specialist service setting to general practice, where this is appropriate and, in the patient's, best interest. When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP (or other primary care prescriber) concerned and the patient to share their care.

Patients and/or carers must be centrally involved in any decision-making process. They should be supported by good quality information that helps them to both come to an informed decision about engagement in a shared care arrangement and sets out the practical arrangements for ongoing supplies of medicines.

The existence of a SCA does not necessarily mean that the GP must agree to and accept clinical and legal responsibility for prescribing; they should only do so if they feel clinically confident in managing that condition. Clinical responsibility for prescribing is held by the person signing the prescription, who must also ensure adequate monitoring.

PLACE IN TREATMENT

Rectal Diazepam is another licensed product available for the treatment of status epilepticus, clusters of seizures and prolonged seizures (lasting 5 minutes or more) in children but using this route can be practically difficult and socially unacceptable. Oromucosal midazolam is as effective as rectal diazepam, is absorbed rapidly through the buccal cavity and has practical advantages of ease and social acceptability in administration.

BUCCOLAM is now the brand of choice for oromucosal midazolam on BSW Formulary (Nov 21). It is licensed for use in children from 3 months to < 18 years. Please prescribe by BRAND NAME. Current patients who are under 10 years of age on Epistatus (unlicensed product) will be reviewed at their next appointment with the specialist nurse and the GP practice will be advised if the patient is being switched to BUCCOLAM. Nurses will then review the cohort of patients on licensed Epistatus age 10 years to <18 years. The aim will be to switch them to Buccolam unless there is a compelling reason why a more concentrated solution is required. Family to be made aware that Epistatus is unlicensed. Buccolam and Epistatus are NOT interchangeable.

Use in adults (>18 years of age):

Please note that no oromucosal midazolam products are licensed for use in adults. Where it is recommended, the GP can prescribe it as an amber shared care medication as per this SCA. The usual recommended dose for an adult is 10mg but prescribers should consult the patients individual care plan if one is in place (or in the clinic letter if there is no care plan).

Responsibilities of Secondary Care Specialist Consultant or Nurse specialist

- Initiate treatment and prescribe the first supply of Buccolam – this should be enough time to allow optimisation of treatment and demonstrate that the patient's response is consistent.
- It is the responsibility of the specialist to ensure that changes to prescription of buccal midazolam are clearly communicated in writing to the GP, family/carer and any other setting in which buccal midazolam is to be held for emergency use e.g. school nursing/pre-school teams
- If a patient is switched to Buccolam by the specialist from Epistatus, it is their responsibility to arrange for corresponding care plans/administration plans to be updated accordingly and old supplies to be returned to the community pharmacy and replaced with the new prescription

- All children under 2 years of age who require oromucosal midazolam will ONLY be initiated on the advice of a Consultant Paediatric Epilepsy specialist.
- Discuss the benefits and side effects of treatment with the patient and/or carers.
- Ensure that the patient/carer understands when and how to give the medication (An identified member of the specialist team such as epilepsy specialist nurse and community/school nurse, will work with the parents / carer to develop an Emergency Treatment Plan for child/young person with epilepsy for administration, train in use, ensure appropriate storage and provide written/verbal advice in a way that the individuals can understand.
- Review concurrent medications for potential interactions prior to initiation.
- Undertake the clinical assessment and relevant monitoring at baseline and during the initiation period.
- Communicate details of treatment to GP (in writing or via secure email) within the first month of treatment and ask the GP whether he or she is willing to participate in shared care.
- Discuss shared care arrangements with the patient/carer, obtain their consent and explain their responsibilities.
- Review the patient's condition and monitor response to treatment regularly where indicated (at least annually).
- Inform the GP after each clinic attendance if there is any change to treatment or monitoring.
- Supply the GP with background information about diagnosis, the reasons for selecting midazolam and details of how to prescribe it, including details of how often doses can be repeated, maximum dose in 24 hours and details of any combination therapy. This summary should be received within 14 days of a hospital outpatient review, in-patient stay or community review.
- Inform the appropriate community nursing service that oromucosal midazolam has been prescribed (by brand name). A Health Care Plan should be put into place by the appropriate community nursing service to support use.
- Ensure that clear arrangements exist for GPs to obtain advice and support.
- Report adverse events to the MHRA: https://yellowcard.mhra.gov.uk/
- Stop treatment where appropriate or provide GP with advice on when to stop.

Responsibilities of GP/Primary Care Prescriber

- Reply to the request as soon as practicable if they are **unable** to support shared care (in writing or via secure email).
- Prescribe oromucosal midazolam after communication with specialist about need for treatment and the formulation to be used and the dose recommended.
- Midazolam is a schedule 3 controlled drug and therefore subject to the requirement for the quantity to be supplied to be written in words and figures and the dose to be on the prescription.
- Undertake ongoing clinical assessment and relevant monitoring following initiation period.
- Annual review and dosage adjustment required as dosage based on age (as advised by specialist nurse).
- Review any new concurrent medications for potential interactions.
- Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Stop treatment on the advice of the specialist.
- Report adverse events to the specialist and MHRA: https://yellowcard.mhra.gov.uk/

Responsibilities of Patient/Carer

- Report to the specialist, community nurse or GP if he or she does not have a clear understanding of the treatment.
- Share any concerns in relation to treatment with medicine. Please contact specialist if you start to need treatment more frequently.
- Report any adverse effects to the specialist, community nurse or GP whilst taking the medicine.
- Attend appointments for clinical review and monitoring.

1. Summary of condition and treatment aims Include links to relevant clinical guidelines e.g. NICE	Epilepsies: diagnosis and management NICE CG137 (Updated 12 May 2021): https://www.nice.org.uk/Guidance/cg137 • Only prescribe oromucosal midazolam for use in the community for children and young people who have had a previous episode of prolonged or serial convulsive seizures. • Over- and potentially inappropriate prescription of emergency benzodiazepines should not be used to alleviate individual, parental or carer's anxiety.

<table>
<tr><td>2. Details of medicine and indication
Please state whether licensed or unlicensed (off-label) use. Note that shared care is generally unsuitable for off-label prescribing unless it is a widely recognised use (e.g. included in BNF)</td><td colspan="2">First-line treatment for children and young people with prolonged (lasting 5 minutes or more) or repeated (three or more in an hour) generalised, convulsive (tonic–clonic, tonic or clonic) seizures in the community. To be used as per patient specific individual agreed protocol and care plan.
Licensed for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 – 6 months (hospital setting only) to < 18 years).
Oromucosal midazolam is a short acting benzodiazepine that offers an alternative to rectal diazepam.
BUCCOLAM must only be used by parents/carers where the patient has been diagnosed with epilepsy.</td></tr>
<tr><td rowspan="4">3. Pharmaceutical aspects</td><td>Route of administration:</td><td>BUCCOLAM is for oromucosal use</td></tr>
<tr><td>Formulation:</td><td>Pre-filled needle-free oral syringe (4 pre-filled syringes in each pack)</td></tr>
<tr><td>Administration details:</td><td>Please refer to SPC and PIL.
BUCCOLAM 10 mg oromucosal solution - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)</td></tr>
<tr><td>Other important information:</td><td>Not for intravenous use.
The oral syringe cap should be removed before use to avoid risk of choking.
SAFETY: MHRA Guidance; The MHRA issued a warning (Drug Safety Update in October 2011) that care was needed if transferring between Epistatus® and Buccolam® due to the differences in strengths between the products.
http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON131931</td></tr>
<tr><td>4. Usual dose and frequency (including details of dose adjustments, e.g. in renal impairment) and duration of therapy
Transfer of monitoring and prescribing to Primary care is normally after the patient is on regular dose and with satisfactory investigation results.
All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
The duration of treatment will be determined by the specialist, based on clinical response and tolerability. Termination of treatment will be the responsibility of the specialist.</td><td colspan="2">Standard dosage:
Buccolam pre-filled oral syringes are available in four colour-coded doses and are prescribed according to the patient's age as follows:
<table>
<tr><th>Age range</th><th>Dose</th><th>Label colour</th></tr>
<tr><td>3 to 6 months hospital setting</td><td>2.5 mg</td><td>Yellow</td></tr>
<tr><td>> 6 months to < 1 year</td><td>2.5 mg</td><td>Yellow</td></tr>
<tr><td>1 year to < 5 years</td><td>5 mg</td><td>Blue</td></tr>
<tr><td>5 years to < 10 years</td><td>7.5 mg</td><td>Purple</td></tr>
<tr><td>10 years to < 18 years</td><td>10 mg</td><td>Orange</td></tr>
</table>
Buccolam® should be given by the oromucosal route (ie the area between the lower gums and inner cheek area of either side of the mouth). The full amount of the solution can be administered on one side but we generally recommend giving approximately half the dose on each side. This should be specified in the individual care plan.
The solution should be administered slowly into the space between the gum and the cheek, avoiding contact with the tongue, and the cheek pressed and massaged immediately to retain the solution and assist with absorption.
Standard advice given to parents – if seizure is not settling 5 minutes after the first dose then call 999 for an ambulance.
Follow advice on individualised care plan. A second dose of midazolam can be given 10 minutes after the first dose but for most children this is only advised in the presence of ambulance crew or a hospital setting. Retain the empty syringe of midazolam to give to the healthcare professional. This will provide information on the dose received by the patient.</td></tr>
</table>

	What to do if a seizure starts again: A second or repeat dose when seizures re-occur after an initial response should not be given without prior medical advice UNLESS its specified in their care plan. **Review and discontinuation of treatment** An ongoing review of the continued need for emergency rescue treatment with oromucosal midazolam should be carried out by **a specialist** at least every 12 months to ensure the seizure management plan is still appropriate and to prevent unnecessary long-term prescribing.
5. Baseline investigations and initial monitoring to be undertaken by specialist	**Baseline investigations** • None required
6. Ongoing monitoring requirements to be undertaken by primary care	• None required
7. Action(s) to be taken by primary care if abnormal result(s)	• If frequency of use increases seek advice from the specialist team
8. Cautions and contraindications Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.	**Cautions** • Buccolam should be used with caution in patients with chronic renal failure as elimination of midazolam may be delayed and the effects prolonged. Careful monitoring of the clinical effects and vital signs is recommended following administration of midazolam in patients with hepatic impairment. Midazolam should be used with caution in patients with chronic respiratory insufficiency because midazolam may further depress respiration. **Contraindications** • Hypersensitivity to the active substance (midazolam), benzodiazepines or to any of the excipients, myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome, severe hepatic impairment.
9. Significant medicine and food interactions and management For a comprehensive list, consult the BNF or Summary of Product Characteristics (SPC)	• Midazolam is metabolized by CYP3A4. Inhibitors and inducers of CYP3A4 have the potential to respectively increase and decrease the plasma concentrations and, subsequently, the effects of midazolam thus requiring dose adjustments accordingly. • Calcium channel blockers, erythromycin, other macrolides, azole antifungals, cimetidine, ranitidine, omeprazole and grapefruit juice reduce the clearance of midazolam. This may result in prolonged duration of sedative effect. • Midazolam may interact with other hepatically metabolised medicinal products, e.g. phenytoin, causing potentiation.
10. Adverse effects and management Include details of incidence, identification, importance and management.	**Adverse Effects (see SPC for full list)** • The most common side effects with Buccolam (seen in 1/100 to 1/10) are sedation, somnolence, depressed levels of consciousness, respiratory depression and nausea and vomiting. All patients receiving midazolam are likely to be drowsy for several hours after administration. • Rare: agitation, restlessness and disorientation have been reported.

11. Advice to patients and carers

The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

- Buccolam pre-filled oral syringes are available in four colour-coded doses and are prescribed according to the age of the patient:

Age range	Dose	Label colour
3 to 6 months hospital setting	2.5 mg	Yellow
> 6 months to < 1 year	2.5 mg	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

- Read Patient Information Leaflet carefully to understand how to give the medication.
- Buccolam UK P2.indd (medicines.org.uk)
- **The oral syringe cap should be removed before use to avoid risk of choking.**
- Seek medical advice from your doctor or pharmacist if further enquiry required.
- Keep the syringe to show to the ambulance staff or doctor after administration.
- Storage: keep the oral syringe in the protective plastic tube. Do not refrigerate or freeze.
- Contact specialist if you start to need to use this medication more frequently.
- Useful patient information including administration video: Buccolam NXP » About Epilepsy

12. Pregnancy and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist.

Pregnancy:

- There are no or limited amount of data from the use of midazolam in pregnant women.
- Midazolam may be used during pregnancy if clearly necessary. The risk for new-born infants should be taken into account in the event of administration of midazolam in the third trimester of pregnancy.

Breastfeeding:

- Midazolam is excreted in low quantities (0.6%) in human milk. As a result, it may not be necessary to stop breast feeding following a single dose of midazolam.

13. Specialist contact information

Contact details	Telephone no.	Email address
Faye Price **RUH Paediatric Epilepsy Nurse Specialist**	01225 825375	Faye.price@nhs.net
Natalie Morabito **Salisbury District Hospital Specialist Epilepsy Nurse**	01722 336 262	natalie.morabito@nhs.net
Susan Mulhall **GWH paediatric epilepsy specialist nurse**	01793 604969 (24 hour voicemail) 01793 605193	susan.mulhall@nhs.net

Other Specialist Contact Information

- Click or tap here to enter text.

14. Additional information

For example, process for when Specialist or GP changes roles; specific issues related to patient age/ capacity/ specific monitoring.

Not applicable

15. References	• Summary of Product Characteristics for Buccolam via https://www.medicines.org.uk/emc/product/7460/smpc • BNF online via https://bnf.nice.org.uk/ • Epilepsies: diagnosis and management NICE CG137 (Updated 12 May 2021): https://www.nice.org.uk/Guidance/cg137
16. To be read in conjunction with the following documents	• NHS England: Responsibility for Prescribing Between Primary & Secondary/ Tertiary Care. Ref 07573, Version 1.0, Published January 2018. Accessed via: https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/ • Click or tap here to enter text.

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