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Guidance for the use of buccal midazolam or rectal diazepam in the treatment of epileptic seizures by neurologists, nurse specialists and health care professionals working with young people and adults within Cumbria.

Scope	Neurologists, Epilepsy nurse specialists
Responsibilities	See guidance detail
Related Policies	Medicines policy POL 001/013 Controlled Drugs Policy POL 001/013/001
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Consultation group	Neurology network
Approval group or committee	Specialist care group governance Safe Medicines Practice Group Cumbria Area Prescribing committee
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Introduction

This document describes the procedures to be followed when either rectal diazepam or buccal midazolam are prescribed for the treatment of convulsive epileptic seizures only. It also contains guidance on the management of epileptic seizures. It is not intended for use in the emergency treatment of seizures of a person who does not have epilepsy e.g. seizures due to alcohol withdrawal. Information in this document does not override clinical judgement or professional liability.

The NICE Guideline CG 137 (2012) (The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care) state that buccal midazolam or rectal diazepam should only be prescribed for use in the community for children, young people and adults who have had a previous episode of prolonged or serial convulsive seizures (NB the definition of "prolonged" or length of time since previous episode will vary according to whether it is a child or adult who is being considered). Buccal midazolam should be administered as first-line treatment in children, young people and adults with prolonged or repeated seizures in the community; rectal diazepam should be administered if preferred or if buccal midazolam is not available.

Prescribing Rescue Medication Responsibilities

- New Patients

Primary care prescribers are not expected to initiate treatment. This should be done by a neurologist. Once a patient has been stabilised GP's may be requested to take over the prescribing of the rescue medication. The clinical and legal responsibility for prescribing should only be accepted if sufficient clinical information has been provided by the initiating prescriber including the brand and preparation of rescue medication.

Neurologist should inform GP, specifying the dose and that the care plan is in place.

- Existing Patients

GP's should not switch patients from one brand to another unless a written request has been received from the patient's neurologist or specialist nurse to make sure training and education has been provided and the Epilepsy Care Plan updated. If for any reason GP's need to initiate a switch they are advised to liaise with the initiating prescriber to ensure the correct dose is prescribed.

Consent to administer Buccal Midazolam should be obtained ahead of where the patient has capacity and documented in the medical notes.

Where the patient does not have capacity to consent, the decision to prescribe Midazolam should be discussed with the multi-disciplinary team and a best interest decision documented the medical notes.

Checklists for Neurologists and Nurse Specialists.

The following two checklists put forward some guidance and recommendations relevant for specialists working within Neurology who prescribe rescue medication. The checklists can also be used by nurse specialists and other nurses who work with people with epilepsy. The evidence is based on BNF guidance (2018), NICE CG 137 (2012), RC PSCH (2017) and NICE NG46 (2016).

The aims of these checklists are to ensure patient safety and prescribe as indicated by current NICE Guidance

The following terms are used in the checklists

Buccal midazolam and rectal diazepam are referred to as rescue medication.

Epilepsy Nurse Service – refers to the Nurse Specialists in Cumbria.

Checklist A: Factors to be considered prior to prescribing rescue medication for the first time

- Is there "convincing and witnessed" evidence of prolonged, tonic-clonic seizures or serial tonic clonic seizures?
- Is the patient's clinical history up to date. (History of mental health, drug, alcohol)?
- **BENZODIAZEPINES – cautions** - (acute pulmonary insufficiency, marked neuromuscular respiratory weakness; sleep apnoea syndrome; unstable myasthenia gravis)
- **Midazolam - Contra-Indications**. (CNS depression, compromised airway) (BNF Nice 2018)
- Is the patient prescribed benzodiazepines? Yes > consider the benzodiazepines load.
- If the patient is prescribed benzodiazepines > obtain an accurate prescription record.
- Is the patient being administered PRN medications or benzodiazepines for seizures?
- **Providing information and advice to people receiving controlled drugs (NICE G46 2016)**
    - New patients prescribed rescue medication should be referred to the epilepsy nurse service or community learning disability service if appropriate to allow the appropriate training to be completed for families and community care staff.
- Patients, prescribed rescue medication should have a comprehensive 'Emergency Rescue Medication Administration Plan' and should be encouraged to keep an accurate seizure record of the seizure type and duration.

Checklist B: Factors to be considered for patients already prescribed rescue medication.

- **New patients and transferred patients** to neurology may not have had a medication review for many years. This is good opportunity to review rescue medication.
- Is there documented witnessed evidence of prolonged or serial tonic clonic seizures?
- Is the patient's clinical history up to date? (History of mental health: drug or alcohol).
- **BENZODIAZEPINES** – cautions - (acute pulmonary insufficiency, marked neuromuscular respiratory weakness; sleep apnoea syndrome; unstable myasthenia gravis).
- **Midazolam -** Contra-Indications. (CNS depression, compromised airway) (BNF Nice) 2018
- Has there been any side effects reported while using rescue medication.
- Is the patient prescribed benzodiazepines? Yes > consider the benzodiazepines load.
- Is the patient prescribed benzodiazepines? (Obtain an accurate record).
- Is the patient being administered PRN medications or benzodiazepines for seizures?
- **Does the patient still require rescue medication?**
  Patients who have not been administered rescue medication for two years or more should have a medication review with their neurologist.
  Discussions should take place with the patient family and staff, and a joint decision made regarding the treatment plan.
- **Providing information and advice to people receiving controlled drugs (NICE G46) 2016**
  New and transferred patients (prescribed rescue medication or discontinued) should be referred to the epilepsy nurse service or community learning disability service if appropriate to allow the appropriate training to be completed for families and community care staff.
- The epilepsy nurse service can liaise with the appropriate health care professionals, when rescue medication is discontinued.
- Patients, prescribed rescue medication should have a comprehensive 'emergency rescue medication administration plan' and should be encouraged to keep an accurate seizure record of the seizure type and duration.

The use of Benzodiazepines in people with a Learning Disability (LD)

Benzodiazepines have been criticised for the potential adverse side effects, including cognitive impairment in long term use in both general and LD populations. As a result they are favoured more for use as rescue treatments. The use of benzodiazepines should be limited in the presence of cognitive deficit or behavioural disorder. Tolerance is a major concern in people with an LD and patients may not have had a medication review for many years. A benzodiazepine may have been prescribed to treat behaviour, mood or anxiety and not withdrawn and if multiple anticonvulsants are prescribed this may manifest as increase in seizures.

Clinicians must be aware of the overall "benzodiazepine load" when prescribing benzodiazepines and monitoring seizures. RC PSYCH (2017). It is recommended that Buccal Midazolam should not be given if another benzodiazepine has been given in the previous 12 hours and vice versa.

Emergency Rescue Medication Administration Plans

An individualised Emergency Rescue Medication Administration Plan should be in place for everyone who is prescribed rescue medication. (Example plan Appendix *).

Consultants and their medical team are responsible for approval and review of each individual's Emergency Rescue Medication Administration Plan. This may also involve a specialist practitioner and input from acute Trust services, and / or the patients GP. If the individual is under the care of a neurologist outside of CPFT this neurologist would be responsible for developing the Emergency Rescue Medication Administration Plan.

People (i.e. staff members, carers and family members) who are competent in the administration of rescue medication are responsible for following each individual's Emergency Rescue Medication Administration Plan.

Emergency Rescue Medication Administration Plans should include: -

• Name

Weight

NHS number

• Seizure descriptions and possible triggers

• Details of the person's consent (or carer's if appropriate) for the administration of the rescue medication (if the person is assessed as being unable to give consent, details of the outcome of a best interests meeting should be documented)

• When rescue medication should be given

• Dose to be given

• How the person usually responds to treatment

• Whether a repeated dose can be given and after what time interval

• Maximum number of doses that can be given in 24 hours

• When an ambulance should be called

• Who else to contact / inform of the seizure

Buccal Midazolam

Buccal Midazolam is available as **Epistatus** or **Buccolam**.

Epistatus contains Midazolam Maleate 10mg in 1ml and is available as pre-filled oral syringes of 2.5mg, 5mg, 7.5mg and 10mg, or as a multi-dose bottle. These formulations are unlicensed and available as a 'special'. A new Epistatus Oromucosal Solution in 1ml prefilled oral syringe is licensed for the treatment or prolonged, acute, convulsive seizures in children and young people aged 10 to less than 18 years.

The preferred Buccal Midazolam preparation used within Cumbria is Buccolam.

Buccolam contains Midazolam Hydrochloride 5mg in 1ml in pre-filled syringes of 2.5mg, 5mg, 7.5mg and 10mg. It is licensed for the treatment or prolonged, acute, convulsive seizures in infants, toddlers, children and young people from 3 months to less than 18 years. It is not licensed for the use in adults. For infants between 3-6 months, treatment should be a hospital setting where monitoring is possible and resuscitation equipment is available.

To avoid medication errors when writing prescriptions, buccal midazolam should be prescribed by brand. The dose should be prescribed in **mg (milligrams)** and **ml (millilitres)**

Buccolam and Epistatus are not interchangeable, there is a high risk of harm should patients receive the incorrect brand and strength of buccal midazolam.

No formulation of buccal midazolam is currently licensed in adults and its use in adults is therefore "off-label" or "off-license"

The person, next of kin and carers should be made aware of the "off-label" or "off-license" status of the medication.

A single dose of buccal midazolam should only be administered. If the seizure has not stopped within 5 minutes of administration of buccal midazolam, emergency medical assistance must be sought and the empty syringe given to the healthcare professional.

A second or repeat dose when seizures re-occur after an initial response should not be given without prior medical advice.

Midazolam ampoules or rectal diazepam tubes should not be used for buccal administration.

Background information

Midazolam is a short acting benzodiazepine. It has been used for the acute management of seizures, as an alternative to rectal diazepam. The NICE CG20 guideline stated "For many individuals and in many circumstances, buccal midazolam is more acceptable than rectal diazepam and is easier to administer. It should be used according to an agreed protocol drawn up by the specialist and only used following training."

Initial effects become apparent after approximately 5 minutes, but may take up to 10 minutes.

Paradoxical reactions e.g. agitation, restlessness and disorientation have been reported following administration. The person may appear sleepy or drowsy for up to 2 hours; if this lasts longer than two hours this should be documented and consideration should be made as to whether future doses should be reduced to a level that reduces sleepiness but stops seizures.

Contraindications include hypersensitivity to the active substance, benzodiazepines or to any excipients, myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome, severe hepatic impairment

Storage

Midazolam does not need to be refrigerated. It should be stored upright at up to 25^{o}c

Midazolam buccal is classified as a Schedule 3 Controlled Drug. The main implications of this classification are on writing an outpatient or discharge prescription. These prescriptions must state the dose, form, strength and a total quantity in words and figures. They will only be valid for 28 days (I.e. the prescription must be dispensed within 28 days of the date on the prescription). Midazolam buccal does not need to be stored in a Controlled Drug cupboard, and records do not need to be kept in a Controlled Drug Register in domiciliary settings.

If Midazolam is required for inpatient use, it must be ordered in the Controlled Drug order book.

The administration of Buccal Midazolam is considered a less invasive procedure. Issues relating to privacy and dignity are less compromised, and in situations where it is not acceptable or convenient to use rectal diazepam.

Rectal Diazepam

Rectal diazepam is available as Diazepam Desitin, Diazepam Rectubes, and Stesolid Rectal Tubes (other preparations may be available).

It is available in pre-filled tubes of 2.5mg, 5mg and 10mg

Rectal diazepam is a benzodiazepine licensed for the treatment of seizures. It has a rapid onset of action (within 5 minutes). Paradoxical reactions e.g. agitation, restlessness and disorientation have been reported following administration. It is not licensed for use in children less than 1 year of age.

Contraindications include Myasthenia Gravis, hypersensitivity to benzodiazepines, severe or acute respiratory insufficiency/depression, sleep apnoea syndrome, severe hepatic insufficiency.

Training and Support

Buccal Midazolam or Rectal Diazepam should not be prescribed until those expected to administer have received appropriate training.

Training should be as described in the Epilepsy Nurse Association (ESNA) (2018) publication, 'Good Practice Guidelines for the Use of Buccal (Oromucosal) Midazolam for Epileptic Seizures in the Community'.

It is recommended that all carers should have received training in epilepsy awareness and the administration of rectal diazepam / buccal midazolam as rescue medication. ESNA recommend that this training should be updated every year. Administration should be in line with the Trust Medicines Policy. Unqualified social care staff must have received training in Epilepsy Awareness, buccal midazolam administration and rectal diazepam administration if appropriate.

It is regarded as best practice that qualified nurses should have received training in buccal midazolam administration.

References

- NICE (2012) CG 137 Epilepsies: diagnosis and management
- BNF (2018) www.bnf.nice.org.uk/drug/midazolam.htm
- NICE (2016) Controlled drugs: safe use and management
- RC Psyc (2016) Prescribing anti-epileptic drugs for people with epilepsy and intellectual disability: (College Report CR206)
- Administration of Epistatus© Buccal Midazolam – 10mg (Base) in 1ml sugar free syrup to people who have epilepsy. Colchester Learning Disabilities Service
- Policy on the safe administration of Epistatus© (Buccal Midazolam – 10mg in 1ml SF Syrup) to People who have Epilepsy. Humber Mental Health NHS Trust 2006.
- Guidance for the use of buccal midazolam or rectal diazepam in the treatment of epileptic seizures: Coventry and Warwickshire Partnership NHS Trust (2016)

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Appendix 1

Guidelines for the administration of Buccal Midazolam

INDIVIDUAL CARE PLAN

Name: NHS No:

Address: DOB:
Date:

Confidential

Please note that this is for use in the community only. If in hospital setting, follow hospital policy.

Epilepsy Emergency Management Plan for the treatment of prolonged seizures and prevention of status epilepticus. If the individual fails to respond and requires hospital admission, please take this protocol, their medication form and a copy of their consultant's latest clinic letter with them.

Please also ensure other Anticonvulsant Medication is taken as prescribed.

Medication prescribed: **Prescribed dosage:** **Route of administration:** **Maximum Dose in 24 hours:**	
When to give Rescue Medication:	
If seizures continue despite Rescue Therapy. **Can a second dose be given?**	

(if so, when?)	
What to do if you can't give Rescue Therapy	
When to call 999	
Precautions, Under what circumstances should Buccal Midazolam not be used?	
What is the usual reaction to Buccal Midazolam?	
Possible adverse reaction/ effects	
Who needs to be informed? **When should the person's Doctor be consulted**?	
Comments	

Personal Details

Persons Name:	**DOB:**
Address:	**Telephone No**:
Weight:	**Allergies:**

Nearest Relative/Carer	
Persons Name:	**Relationship:**
Address:	**Telephone No:**
General Practitioner	**Consultant**
Name: **Address:** **Telephone No:**	**Name:** **Position:** **Address:** **Telephone No:**

Specialist nurse
Name: **Positon:** **Address:** **Telephone No:**

Seizure Descriptions

Description of seizure that may require Buccal Midazolam: **Usual duration:**

Description of seizure that may require Buccal Midazolam: **Usual duration:**

Possible reactions to Buccal Midazolam?

• Sedation, relaxation, amnesia. • Most individuals tolerate Buccal Midazolam with no severe reactions. • After administration the person must be observed until they have fully recovered. • Although it is rare this medication can sometimes cause breathing difficulties if you are concerned about the persons breathing you should call 999. • It is recommended when giving **the FIRST dose of Midazolam** you also call 999.

What should be done if there are any difficulties in the administration of the Midazolam? (eg. Dribbling, missing the mouth due to sudden jerk/convulsions)
• If there are any difficulties administering Buccal Midazolam, call **999**

Who should administer the Buccal Midazolam
• Only individuals who have been given up to date training.

Who should be informed
• Family / carers if requested • GP / Consultant / Specialist nurse at the next review • Other (please state)

This plan should be checked and agreed by the consultant prescribing the medication

Consultant name:
Position:
Signature: **Date:**

Plan developed by:
Position:
Signature: **Date:**

This treatment plan should be reviewed on a 12-monthly basis or when necessary. Review date:

Please use this space to record any capacity / best interest considerations

Appendix 2

Procedure for the administration of buccal midazolam

1. Action - Hand decontamination should be carried out, as per Trust Policy, prior to carrying out any procedure – if possible. It is recognized that this is an emergency procedure.
   Rationale - To minimize cross infection and promote health.

2. Action - Note the time seizure starts and if possible write it down. Follow the person's specific care plan or Epilepsy Management Plan (EMP) or protocol for instruction on when medication should be given – usually 5 minutes after start of seizure.
   Rationale - To ensure accurate and effective delivery of the medication to the person.

3. Action - Check when the person last had buccal midazolam as rescue treatment, ensuring that the minimum time interval between treatments has elapsed.
   Rationale - To ensure accurate and effective delivery of the medication to the person.

4. Action - Check the prescription sheet/pharmacy label against the drug, dosage and expiry date. Take extra care to check the strength of the product is correct.
   Rationale - To ensure accurate and effective delivery of the medication to the person.
5. Action - Support the head, open the person's mouth, place syringe into buccal cavity and administer half the contents.
   Rationale - To increase the area for absorption of medication, which may increase speed of absorption.

6. Action - Repeat above step, administering the remainder of the contents to the buccal cavity on the other side of the mouth. NB: If person is on their side (for example lying in recovery position, or a focal seizure is forcing them onto their side) give all the medicine into the buccal cavity that they are lying on. Do not attempt to give half in each side.
   Rationale - To increase the area for absorption of medication, which may increase speed of absorption. To minimize risk of medication being lost, swallowed or inhaled.

7. Action - When Buccal Midazolam is administered for the FIRST TIME, please ring an ambulance immediately.
   Rationale -To ensure safety of person having the medication for the first time as we don't know how they will respond to it.

8. Action - Ensure the person is allowed sufficient recovery time.
   Rationale -To ensure person's safety following administration of medication.

9. Action - Do not give a subsequent dose if the dose is spilt or spat out unless the care plan/Epilepsy Management Plan (EMP)/protocol details otherwise.
   Rationale -To minimize risk of person receiving incorrect/extra dose.

10. Action - Monitor for any adverse effects, effectiveness or lack of effectiveness of the dose. Follow the care plan/EMP/protocol if dose ineffective.
    Rationale -To ensure person's safety following administration of medication.

11. Action - If the seizure does not stop within 5 minutes of giving Buccal Midazolam medical assistance should be requested.
    Rationale -To ensure the person can receive further treatment under medical supervision.

12. Action - Record the procedure, care, outcome and actions in the person's care records.
    Rationale -To maintain best practice regarding record keeping (NMC 2008).

13. Action - Record the time of administration and effects of buccal midazolam in the care plan/EMP (and prescription sheet if used), adding signature.
    Rationale -To ensure good communication.

14. Action - Stay with the person until the seizure has stopped and maintain their safety. Place the person in the recovery position. Allow the person to recover and rest, Monitor for side effects
    Rationale – maintain a safe environment for the person after administration of buccal midazolam.

Dial 999 for an ambulance: -

- **If you have concerns about the individual's breathing**
- **If they become injured and you have concerns for their safety**
- **Or as indicated in the seizure management plan**
- **If you have administered more than the prescribed dose**

Appendix 3

Procedure for the administration of rectal diazepam

1. Action - Hand decontamination will be done, as per Trust Policy, prior to carrying out any procedure – if possible. It is recognized that this is an emergency procedure.
   Rationale -To minimize cross infection and promote health.

2. Action - Note the time seizure starts and if possible write it down. Follow the individual's specific care plan or Epilepsy Management Plan (EMP) or protocol for instruction on when medication should be given – usually 5 minutes after start of seizure.
   Rationale -To ensure accurate and effective delivery of the medication to the individual.

3. Action - Check when the person last had rectal diazepam as rescue treatment, ensuring that the minimum time interval between treatments has elapsed.
   Rationale -To ensure accurate and effective delivery of the medication to the individual.

4. Action - Check the prescription sheet/pharmacy label against the drug, dosage and expiry date.
   Rationale -To ensure accurate and effective delivery of the medication to the individual.

5. Action- Lie the adult on their side (or according to care plan). If the person is a child, refer to individual protocol. Ensure the dignity of the person is maintained throughout.
   Rationale -To make the person as comfortable as possible and maintain dignity.

6. Action -Put on disposable gloves.
   Rationale -To minimize cross infection.

7. Action -Remove the cap on the tube and gently insert the entire length (or half if three years of age or younger) of the nozzle into the rectum, pointing the spout downwards and squeezing the tube firmly between index finger and thumb.
   Rationale -To ensure the correct dose is administered.

8. Action - Keep the pressure on the tube for a few seconds.
   Rationale -To ensure the correct dose is administered.

9. Action -Keeping the tube squeezed, withdraw tube from rectum. Press the buttocks together gently for a time.
   Rationale -To ensure the correct dose is administered.

10. Action - Dispose of tube and gloves as per waste disposal policy.
    Rationale -To ensure environment is protected.

11. Action -Ensure the person is allowed sufficient recovery time.
    Rationale - To ensure individual's safety following administration of medication.

12. Action - Monitor for any adverse effects, effectiveness or lack of effectiveness of the dose. Follow the epilepsy management plan (EMP)/protocol if dose ineffective (if there is no specific guidance and the dose is ineffective, dial 999 for an ambulance.)
    Rationale -To ensure individual's safety following administration of medication.

13. Action - Record the procedure, care, outcome and actions in the individual's care records.
    Rationale -To maintain best practice regarding record keeping (NMC 2008).

14. Action - Record the time of administration and effects of rectal diazepam in the care plan, EMP (and prescription sheet if used), adding signature.
    Rationale - To ensure good communication

15 Action stay with the person until the seizure has stopped and maintain their safety

    Place the person in the recovery position
    Allow the person to recover and rest
    Monitor for side effects
    Inform relevant health care staff such as GP – (refer to care plan)

    Rationale – maintain a safe environment for the patient after administration of buccal midazolam

Dial 999 for an ambulance: -

- **If you have concerns about the individual's breathing**
- **If they become injured and you have concerns for their safety**
- **Or as indicated in the seizure management plan**
- **If you have administered more than the prescribed dose**