This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Administration of buccal midazolam by registered Paramedics and Nurses for the management of seizures

BrisDoc Healthcare Services

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1 May 2020	New template
Version 1.1 March 2022	Inclusion and exclusion criteria updated to: • include neonates from birth; • note buccal/PR routes first line in babies/small children. Off label section updated to reflect use in under 3 months. Dosage section updated to reflect updated JRCALC guidance to include neonates from birth. Guidance added on handling of newly added doses.
Version 1.1 September 2023	Reviewed – No Changes – Dates of review and expiry updated

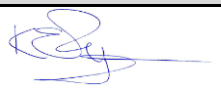
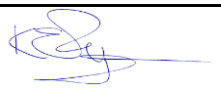
This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

This PGD template has been peer reviewed by the Ambulance Service critical care PGD Short Life Working Group in accordance with their Terms of Reference. It has been approved by the National Ambulance Service Medical Directors (NASMeD) in April 2020.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Sumithra Maheswaran	Pharmacist
Sue Oakley (V1.0)	Pharmacist
Elizabeth Miller (V1.1)	Pharmacist
Tim Edwards	Consultant paramedic
Paul Brennan	Advanced Paramedic
Julie Ormrod	Consultant Paramedic
Stuart Cox	Critical Care Nurse
Jez Pinnell	Doctor
Philip Cowburn	Doctor
Tracy Rogers	Associate Director Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Samrina Bhatti (V1.0)	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Medical Director		01.05.22
Senior pharmacist	Lead Pharmacist		01.05.22
Senior representative of professional group using the PGD	Director of Nursing, Allied Health Professionals and Governance		01.05.22
Person signing on behalf of authorising body	Medical Director		01.05.22

1. Characteristics of staff

Qualifications and professional registration	Professional registration with HCPC as a Paramedic. Professional registration with NMC as a Nurse or Midwife. Current contract of employment with BrisDoc healthcare Services as non-prescribing registered clinician.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training as defined by the employing organisation and successfully completed the competencies to undertake clinical assessment of the individual leading to diagnosis of the conditions listed. They must be competent to recognise and manage unintended but expected side effects including such as anaphylaxis.
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
Ongoing training and competency	Organisation PGD or medication training as required by employing Trust/organisation. Annual anaphylaxis and resuscitation training. Completion and submission of Continuous Professional Development (CPD) as required by HCPC or NMC.
The decision to administer any medication rests with the individual registered practitioner who must abide by the PGD and any associated organisation policies.	
In the context of the clinical scenario described in this PGD the individual will not be able to make an informed choice nor consent to treatment. Therefore, the clinician should act in the best interests of the individual at all times and within their professional competency and code of conduct.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Treatment of seizures in adults and children from birth as detailed below.

Criteria for inclusion	• Treatment of seizures in adults, children and neonates from birth (weighing 3.5kg or greater) who:
	  • Have convulsions lasting 5 minutes or more and who are still convulsing where IV access cannot be established (note in babies/small children consider buccal/PR routes first line).
	  • Have had three or more convulsions in an hour and who are still convulsing where IV access cannot be established (note in babies/small children consider buccal/PR routes first line).
	• Treatment of eclamptic convulsion - initiate treatment if the seizure lasts over 2-3 minutes or is recurrent where IV access cannot be established.

Criteria for exclusion	• IV access established. • Babies weighing less than 3.5kg • Prior administration of two doses of a benzodiazepine during the current episode of care (including those given by carer from an individual's own medication). • Known hypersensitivity to benzodiazepines or to any component of the product - see Summary of Product Characteristics • Currently presenting with Psychogenic Non-Epileptic Seizure (PNES) – follow individualised treatment plan.
Cautions including any relevant action to be taken	**Where a caution is present the practitioner should be aware of the possible effects of administration but should continue to administer where the benefit outweighs risk. Contact the local senior on call clinician for advice on the below if required.** • Uncorrected hypoglycaemia or hypoxia. If the seizure is due to hypoxia or hypoglycaemia ensure that this is corrected. • Concomitant use of opioids - increased risk of adverse effects including respiratory depression. • Known myasthenia gravis or any other marked neuromuscular respiratory weakness. • Known sleep apnoea syndrome. • Known concomitant use of anti-depressants or other CNS depressants or recent alcohol consumption – may potentiate adverse effects. • Breast-feeding - midazolam passes in low quantities into breast milk. • Pregnancy - the administration of high doses of midazolam in the last trimester of pregnancy or during labour has been reported to produce maternal or foetal adverse reactions. Use during pregnancy if clearly necessary. • A delayed respiratory depression as a result of high active metabolite concentrations may be observed in the 1-6 months age group.

	• Chronic respiratory insufficiency: midazolam may cause respiratory depression. • Renal impairment: elimination of midazolam may be delayed and the effects prolonged. • Hepatic impairment: clearance of midazolam may be delayed and the effects prolonged. • Impaired cardiac function: clearance of midazolam may be delayed. Life-threatening incidents are more likely to occur in those with pre-existing respiratory insufficiency or impaired cardiac function, particularly when a high dosage is administered. • Extreme caution should be use if administering midazolam to individuals with personality disorders. Benzodiazepines have a disinhibiting effect. • Known history of drug or alcohol abuse.
Action to be taken if the individual is excluded	• Seek senior clinical support immediately. • Record reasons for exclusion in clinical record and ensure in handover to receiving hospital.
Arrangements for referral for medical advice	• Babies weighing less than 3.5kg • If the seizures are not controlled within dosage regimen of the PGD seek senior clinical support immediately. • Individuals treated with benzodiazepines should always be transported to hospital unless their care plan states otherwise. • If individual has capacity to consent and refuses hospital transfer, then seek senior clinical support immediately. • Where an individual is left at home, every effort must be made to ensure they are in the care of a responsible adult. The responsible adult must be told to call 999 immediately if the individual experiences further seizures or their condition deteriorates in any way.

3. Description of treatment

Name, strength & formulation of drug	Oromucosal solution containing midazolam hydrochloride **5mg in 1ml** (e.g. Buccolam®) as 2.5mg, 5mg, 7.5mg and 10mg pre-filled syringes
Legal category	CD POM Schedule 3 No Reg
Off-label use	• Buccolam® - off-licence use in adults aged 18 years and over and under 3 months of age The use of buccal midazolam in adults and children from birth is supported.
Route / method of administration	• **First dose (consider any prior doses of benzodiazepine administered by parent, carer or other healthcare professional as one of the two doses in total that may be administered):** Dose as per below table. • **Second dose (as above consider any prior doses of benzodiazepine administered):** Dose as per below table.

<table>
<tr><td></td><td>The full amount of solution should be inserted slowly into the space between the gum and the cheek. If necessary (for larger volumes and/or smaller individuals), approximately half the dose should be given slowly into one side of the mouth, then the other half given slowly into the other side.

If individual continues to convulse 10 minutes after the second dose seek additional clinical support and advice (see ‘Arrangements for referral for medical advice’).</td></tr>
<tr><td>Dose and frequency of administration</td><td>Oromucosal solution containing midazolam hydrochloride 5mg in 1ml (e.g. Buccolam®) as 2.5mg, 5mg, 7.5mg and 10mg pre-filled syringes
<table>
<tr><th>Age</th><th>Dose</th><th>Concen-tration</th><th>Volume</th><th>Repeat Dose</th><th>Dose Interval</th><th>Maximum Dose</th></tr>
<tr><td>10 years and over/ adults</td><td>10 milligrams</td><td>5mg in 1ml</td><td>2ml pre-filled syringe</td><td>10 milligrams</td><td>10 minutes</td><td>20 milligrams</td></tr>
<tr><td>5 – 9 years</td><td>7.5 milligrams</td><td>5mg in 1ml</td><td>1.5ml pre-filled syringe</td><td>7.5 milligrams</td><td>10 minutes</td><td>15 milligrams</td></tr>
<tr><td>1 – 4 years</td><td>5 milligrams</td><td>5mg in 1ml</td><td>1ml pre-filled syringe</td><td>5 milligrams</td><td>10 minutes</td><td>10 milligrams</td></tr>
<tr><td>3 – 11 months</td><td>2.5 milligrams</td><td>5mg in 1ml</td><td>0.5ml pre-filled syringe</td><td>2.5 milligrams</td><td>10 minutes</td><td>5 milligrams</td></tr>
<tr><td>1 day – 2 months who weigh ≥3.5kg</td><td>1.25mg</td><td>5mg in 1ml</td><td>0.25ml*</td><td>1.25mg</td><td>10 minutes</td><td>2.5 milligrams</td></tr>
</table>
* Doses for children 0 to 3 months cannot be achieved using the Buccolam® pre-filled syringe range. The dose of 1.25mg must be measured and excess volume (0.25ml from a 2.5millgram pre-filled syringe) discarded before the dose is administered. Measure and discard using an appropriate enteral syringe as per local guidelines.</td></tr>
<tr><td>Duration of treatment</td><td>Single episode of care.</td></tr>
<tr><td>Drug interactions</td><td>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website or BNF: www.medicines.org.uk https://bnf.nice.org.uk/

There are many drug-drug interactions reported with midazolam as it is metabolized by CYP3A4. This does not affect the dose of midazolam to be given under this PGD but may lead to reduced clearance/the effects of any concurrent interacting medication. Therefore it is important that a full, current drug history is taken and supplied to the receiving medical team so a review of any interaction with current medications can be undertaken.</td></tr>
<tr><td>Identification & management of adverse reactions</td><td>A detailed list of adverse reactions is available in the product’s SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Common adverse effects include:</td></tr>
</table>

	• Sedation, somnolence, depressed levels of consciousness • Respiratory depression • Nausea and vomiting • Midazolam may cause anterograde amnesia. • Buccal administration can provoke gagging, coughing and aspiration
Management of and reporting procedure for adverse reactions	• The practitioner acting under this PGD must ensure that all necessary drugs and equipment are available for immediate treatment should a hypersensitivity reaction occur and must be trained to manage anaphylaxis and be prepared to support ventilation including immediate availability of equipment to support airway management and ventilation. • Healthcare professionals and indiviudals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all ADRs in the clinical record. • Report via organisation incident policy.
Advice / follow up treatment	If the individual is not transferred to hospital inform the individual/parent/carer of possible side effects and their management (e.g. increased drowsiness, do not drive or operate machinery if affected, do not drink alcohol). The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.
Special considerations / additional information	• For oral use only. • The oral syringe cap should be removed before use to avoid risk of choking. • No needle, intravenous tubing or any other device for parenteral administration are compatible and must not be attached to the oral syringe. • The two available preparations are different strengths so caution should be taken to check the concentration. • Oral syringes are not graduated so the correct syringe for the dose required should be selected.
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records	Record: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of practitioner • name of medication administered • date of administration • dose, form and route of administration • quantity administered • advice given, including advice given if excluded or

	declines treatment • details of any adverse drug reactions and actions taken • if treatment did not proceed under this PGD record reason/s why and actions taken • supplied via Patient Group Direction (PGD) All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references (accessed December 2019)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • Reference guide to consent for examination or treatment https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • JRCALC guideline https://www.jrcalc.org.uk/ • Resuscitation Council (UK) www.resus.org.uk • Safety in Lactation https://www.sps.nhs.uk/articles/safety-in-lactation-drugs-used-in-status-epilepticus/

Appendix A - Registered health professional authorisation sheet

PGD Name/Version: Midazolam V1.1 Valid from: 01.05.22 Expiry: 15.12.2025

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of BrisDoc Healthcare Services for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD. Practice and application must be compliant with the medicines management policy.