## PATIENT GROUP DIRECTION (PGD)

**Administration of diazepam solution by intravenous (IV)/intraosseous (IO) injection by registered Paramedics and Nurses for the management of seizures**

The Specialist Pharmacy Service (SPS) has developed this PGD with relevant national professional bodies and experts to facilitate the safe and efficient supply and administration of medicines. It has been produced in line with legislation, national recommendations and acknowledged best clinical practice.

Organisations must authorise this PGD according to their clinical governance processes before it can be used. This is in accordance with The Human Medicines Regulations 2012 Schedule 16 Part 2.

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off provided. Sections 2 and 7 must be completed by the authorising organisation.

This PGD can only be used by registered health professionals identified in Section 3, subject to any limitations to authorisation detailed by the authorising organisation in Section 2.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person in accordance with Human Medicines Regulations 2012. It is neither valid nor legal without this.

Individual registered health professionals must be authorised by name under the current version of this PGD before working according to it.

Registered health professionals and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of SPS PGDs for authorisation can be found at [www.sps.nhs.uk](http://www.sps.nhs.uk)

Any concerns regarding the content of this PGD should be addressed to:

LNWH-tr.MUS-SpecialistPharmacyService@nhs.net

**Documentation details**

|  |  |
| --- | --- |
| Reference no: | NAT 004 |
| Version no:  | 1.0 |
| Valid from: | March 2020 |
| Review date: | September 2022 |
| Expiry date: | March 2023 |

**Change history**

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| **Version number** | **Change details** | **Date** |
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**Glossary**

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| **Abbreviation**  | **Definition** |
| JRCALC | Joint Royal Colleges Ambulance Liaison Committee |

1. **PGD template development**

This PGD template has been developed by the following health professionals on behalf of Specialist Pharmacy Service (SPS):

|  |  |  |  |
| --- | --- | --- | --- |
| **Developed by** | **Name** | **Signature** | **Date** |
| **Pharmacist** | Rosie England |  *Electronic signature held on file* | 19/11/2019 |
| **Doctor** | Mr Andy Curran | *Electronic signature held on file* | 19/11/2019 |
| **Paramedic** | Daniel Haworth | *Electronic signature held on file* | 25/11/2019 |
| **Nurse** | Simon Standen  | *Electronic signature held on file* | 12/12/2019 |

This PGD template has been peer reviewed by registered paramedics and nurses Short Life Working Group in accordance with their Terms of Reference. It has been approved by The National Ambulance Service Medical Directors (NASMeD) in December 2019 and ratified by the Regional Medicines Optimisation Committee (RMOC) in January 2020.

**Short Life Working Group Membership**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Rosie England\* | Pharmacist |
| Ian Wilmer  | Advanced Paramedic Practitioner (Critical Care) |
| Dan Haworth\* | Consultant paramedic |
| Simon Standen | Consultant paramedic and Nurse  |
| Dr Dave Macklin | Doctor |
| Mr Andy Curran\* | Doctor |
| Tracy Rogers | Associate Director Specialist Pharmacy Service  |
| Jo Jenkins  | Specialist Pharmacist PGDs Specialist Pharmacy Service |
| Samrina Bhatti (Working Group Co-ordinator) | Chief Pharmaceutical Officer’s Clinical Fellow Specialist Pharmacy Service |

\*Core working group members and PGD signatories.

1. **Organisational authorisations**

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

**INSERT AUTHORISING BODY NAME** authorises this PGD for use by the services or providers listed below:

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| **Authorised for use by the following organisation and/or services** |
|   |
| **Limitations to authorisation** |
| E.g. Any local limitations the authorising organisation feels they need to apply in-line with the way services are commissioned locally or limiting the professions within an organisation who may operate under the PGD. For example ‘This organisation does not authorise the use of this PGD by …’  |

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| **Organisational approval (legal requirement)** |
| **Role** | **Name**  | **Sign** | **Date** |
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| **Additional signatories according to locally agreed policy** |
| **Role** | **Name**  | **Sign** | **Date** |
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Local enquiries regarding the use of this PGD may be directed to…………….

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets/templates may be used where appropriate in accordance with local policy.

1. **Characteristics of staff**

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| **Qualifications and professional registration** | * Professional registration with HCPC as a Paramedic.
* Professional registration with NMC as a Nurse.
* Current contract of employment within an NHS Trust/organisation or NHS commissioned service as a Paramedic or Nurse.
 |
| **Initial training** | * The registered healthcare professional authorised to operate under this PGD must have undertaken organisation approved training and successfully completed the competencies to undertake clinical assessment of patients leading to diagnosis of the conditions listed. They must be competent to recognise and manage unintended but expected side effects including anaphylaxis.
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| **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](https://www.nice.org.uk/guidance/mpg2/resources)
* 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.
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| **Ongoing training and competency** | * Organisation approved PGD or medication training as required by employing Trust/organisation.
* Anaphylaxis and resuscitation training in line with organisation requirements.
* Completion and submission of Continuous Professional Development (CPD) as required by the relevant professional body.
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| 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 patient will not be able to make an informed choice nor consent to treatment. Therefore, the clinician should act in the best interests of the patient at all times and within their professional competency and code of conduct.** |

1. **Clinical condition or situation to which this PGD applies**

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| **Clinical condition or situation to which this PGD applies** | Treatments of seizures in adults and children (all ages) where IV or IO access is available in line with JRCALC guidance. |
| **Criteria for inclusion** | * Treatment of seizures in adults and children (all ages) who:
	+ Have convulsions lasting 5 minutes or more and who are still convulsing.
	+ Have had three or more convulsions in an hour and who are still convulsing.
	+ Eclamptic convulsion - initiate treatment if the seizure lasts over 2-3 minutes or is recurrent.
* Symptomatic cocaine toxicity (severe hypertension, chest pain or convulsions).
 |
| **Criteria for exclusion** | * Known hypersensitivity to benzodiazepines or to any component of the product (see [Summary of Product Characteristics](https://www.medicines.org.uk/emc)
* Prior administration of two doses of a benzodiazepine (any route) during the episode of care (including those given by carer from patient’s own medication).
* Currently presenting with Psychogenic Non-Epileptic Seizure (PNES) – follow individualised treatment plan.
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| **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.* Uncorrected hypoglycaemia or hypoxia. If the seizure is due to hypoxia or hypoglycaemia ensure that this is corrected.
* Patients with known myasthenia gravis or any other marked neuromuscular respiratory weakness.
* Patients with known sleep apnoea syndrome
* Debilitated or frail elderly patients old may require a reduced dose (see dosage section).
* Concomitant use of opioids - increased risk of adverse effects including respiratory depression.
* Patients taking anti-depressants or other CNS depressants or recent alcohol consumption – may potentiate adverse effects.
* Benzodiazepines should be used with caution in patients with chronic respiratory insufficiency because they may further depress respiration.
* Benzodiazepines should be used with caution in patients with renal impairment. No dose adjustment is required, however, in patients with chronic renal failure the elimination of benzodiazepines may be delayed and the effects prolonged.
* Hepatic impairment reduces the clearance of benzodiazepines with a subsequent increase in terminal half-life. Therefore, the clinical effects may be stronger and prolonged, hence careful monitoring of the clinical effects and vital signs is recommended following administration of benzodiazepines in patients with hepatic impairment.
* In patients with impaired cardiac function clearance of benzodiazepines may be decreased. 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 diazepam to patients with known personality disorders - benzodiazepines have a disinhibiting effect.
* Known history of drug or alcohol abuse.
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| **Action to be taken if the patient is excluded** | * Follow JRCALC and local service procedure.
* Record reasons for exclusion in patient notes and ensure in handover to receiving hospital.
 |
| **Arrangements for referral for medical advice** | * If the seizures are not controlled within dosage regimen of the PGD follow JRCALC and/or local service procedure.
* Patients treated with benzodiazepines should always be transported to hospital unless their care plan states otherwise.
* If patient has capacity to consent and refuses hospital transfer then follow locally agreed pathway/JRCALC.
* Where patients are 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 patient experiences further seizures or their condition deteriorates in any way.
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1. **Description of treatment**

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| **Name, strength & formulation of drug** | Diazepam 5mg in 1ml solution for injection |
| **Legal category** | CD Benz POM |
| **Route / method of administration** | **Intravenous/intraosseous injection:*** Slow intravenous (IV)/intraosseous (IO) injection

Dose may be titrated in symptomatic cocaine toxicity as described below. |
| **Dose and frequency of administration** | **Seizure - intravenous/intraosseous injection:****Adults and children 10 years and over**:* Administer by slow IV/IO injection over 2 minutes.
* Reduce the dose by half in frail and debilitated patients and in patients aged 70 years and over.

**Children under 10 years**: * Administer over 3 -5 minutes by slow IV/IO injection.

**The full dose should be given** at the appropriate times for seizures. It is not appropriate to either:* gradually 'titrate the dose upwards' or
* to only give a partial dose if the convulsion stops (once started, even if the convulsion stops, that dose must be given). Giving partial doses is likely to result in convulsion recurrence.

**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 and administer full dose.**Second dose 10 minutes after first dose (as above consider any prior doses of benzodiazepine administered):** Dose as per below table and administer full dose.If patient continues to convulse 10 minutes after the second dose seek additional clinical support and advice (see ‘Arrangements for referral for medical advice’). Transport as soon as possible**Dosage table:**

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| --- | --- | --- | --- |
| **Age** | **Initial dose/repeat dose** | **Drug volume** | **Maximum dose** |
| Adults aged 70 year and over or frail or debilitated patients irrespective of age  | 5mg | 1ml | 10mg |
| 10-69 years | 10mg | 2ml | 20mg |
| 9 years | 9mg | 1.8ml | 18mg |
| 8 years | 8mg | 1.6ml | 16mg |
| 7 years | 7mg | 1.4ml | 14mg |
| 6 years | 6.5mg | 1.3ml | 13mg |
| 5 years | 6mg | 1.2ml | 12mg |
| 4 years | 5mg | 1ml | 10mg |
| 3 years | 4.5mg | 0.9ml | 9mg |
| 2 years | 4.0mg | 0.8ml | 8mg |
| 18 months- 1 years | 3.5mg | 0.7ml | 7mg |
| 9-17months | 3mg | 0.6ml | 6mg |
| 6-8 months | 2.5mg | 0.5ml | 5mg |
| 3-5 months | 2mg | 0.4ml | 4mg |
| 1-2 months | 1.5mg | 0.3ml | 3mg |
| Birth-27 days | 1.0mg | 0.2ml | 2mg |

**Symptomatic cocaine toxicity - intravenous/intraosseous injection:****Adults 12 years and over:** * Administer by slow IV/IO injection over 2 minutes.
* Dose must be **titrated to response** in symptomatic cocaine toxicity where patients are not convulsing.
* Reduce the dose by half in frail and debilitated patients and in patients aged 70 years and over.

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| --- | --- | --- | --- |
| **Age** | **Initial dose/repeat dose** | **Drug volume** | **Maximum dose** |
| Adults aged 70 year and over or frail or debilitated patients irrespective of age  | Gradually titrate to 5mg | 1ml | 10mg |
| 12-69 years | Gradually titrate to 10mg | 2ml | 20mg |

In all cases be prepared to support ventilation, treat hypotension and monitor for arrhythmia. |
| **Duration of treatment** | Single episode of care.  |
| **Drug interactions** | A detailed list of drug interactions is available in the SPC or BNF: www.medicines.org.uk <https://bnf.nice.org.uk/>There are many drug-drug interactions reported with diazepam as it is partly metabolized by CYP3A4. This does not affect the dose of diazepam 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.  |
| **Identification & management of adverse reactions** | A detailed list of adverse reactions is available in the product’s SPC [www.medicines.org.uk](file:///C%3A%5CUsers%5CJJenkins1%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CIO3DM0XR%5Cwww.medicines.org.uk)Common adverse effects include:* Hypotension may occur. This may be significant if the patient has to be moved from a horizontal position to allow for extrication. Caution should therefore be exercised and consideration given to either removing the patient flat or, if fitting has stopped and it is considered safe, allowing a 10 minute recovery period prior to removal.
* Drowsiness and light-headedness, confusion and unsteadiness (especially in the elderly)
* Occasionally amnesia may occur.
* Ataxia, impaired motor ability, tremor.
* Respiratory depression may occur, especially in the presence of alcohol
* Opioid drugs enhance the cardiac and respiratory effect of diazepam.
* Intravenous injections of diazepam may be associated with local reactions and thrombophlebitis. Venous thrombosis may occur. This is more common with the solution preparation than the emulsion.

A detailed list of adverse reactions is available in the product SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) |
| **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/or support ventilation.
* Healthcare professionals and patients/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 patient’s medical record.
* Report via organisation incident policy.
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| **Patient advice / follow up treatment** | * If patient 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.
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| **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](http://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
* anatomical site of administration (if indicated)
* advice given, including advice given if excluded or declines treatment
* details of any adverse drug reactions and actions taken
* supplied via Patient Group Direction (PGD)

Records should be signed and dated (or a password controlled e-records). 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. |

1. **Key references**

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| **Key references**  | * 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](http://www.resus.org.uk)
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1. **Practitioner authorisation sheet**

**Administration of diazepam solution for injection by registered Paramedics and Nurses for the management of seizures V1**

**Valid from: March 2020 Expiry: March 2023**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

**Practitioner**

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.

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| **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** |
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**Authorising manager**

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| **I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of INSERT NAME OF ORGANISATION 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 practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.