

This patient group direction (PGD) must only be used by registered health 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)

For the administration or supply of

Midazolam 1mg/ml IV / IO

By registered health care professionals for

Adjunct in the management of severe pain

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 50

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	<ul style="list-style-type: none"> Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy
Initial training	<ul style="list-style-type: none"> Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	<ul style="list-style-type: none"> • Adjunct in the management of severe pain • Adjunct to reduce the dysphoric effects (emergence phenomenon) of ketamine administration
Inclusion criteria	<ul style="list-style-type: none"> • Adjunct in the management of severe pain • Adjunct to reduce the dysphoric effects (emergence phenomenon) of ketamine administration • Age 12 years and above
Exclusion criteria	<ul style="list-style-type: none"> • Children under twelve (12) years • Known hypersensitivity to midazolam • Pregnancy
Cautions (including any relevant action to be taken)	<ul style="list-style-type: none"> • Cardiac disease, in particular, heart failure and arrhythmias. • Pulmonary hypertension • Infective endocarditis • Rheumatic or Carcinoid heart disease • Congenital abnormalities (e.g. tetralogy of Fallot, ventricular septal defect, valvular pulmonic stenosis) • Pulmonary valve repair • Chronic obstructive pulmonary disease • Extra caution should be exercised in the presence of any other form of cerebral depressant
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated

8. Details of the medicine

Name, form and strength of medicine	Midazolam 1mg/1ml
Legal category	Prescription Only Medicine (POM) schedule 3
Indicate any <u>off-label use</u> (if relevant)	None
Route/method of administration	Intravenous (IV) or intraosseous (IO)

Dose and frequency	<p>12 years old to 59 years old</p> <ul style="list-style-type: none"> • 1mg IV/IO followed by a 10ml saline flush • Dose interval 3 minutes • Maximum cumulative dose 5mg <p>60 years and older</p> <ul style="list-style-type: none"> • 0.5mg IV/IO followed by a 10ml saline flush • Dose interval 3 minutes • Maximum cumulative dose 2.5mg
Quantity to be administered and/or supplied	As per dose
Maximum or minimum treatment period	Single episode of care
Storage	Store at Room temperature
Adverse effects	<ul style="list-style-type: none"> • Respiratory depression • Apnoea • Coma • Drowsiness • Confusion and agitation • Paradoxical reactions including aggressive behaviour, hallucinations and increased anxiety • Hypotension • Chest pain • Bradycardia • Cardiac arrest • Slurred speech • Tremor • Appetite suppression • Sleep disturbance • Transient retrograde amnesia • Dry mouth • Jaundice
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

9. Patient information

Verbal/Written information to be given to patient or carer	<ul style="list-style-type: none"> • Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

10. Appendix A

References
<ol style="list-style-type: none">1. British National Formulary (BNF) available online: https://bnf.nice.org.uk2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk3. Current Health Care Professions Council standards of practice4. General Pharmaceutical Council standards5. The General Optical Council6. Electronic medicines compendium available online: https://www.medicines.org.uk

11. Appendix B

Health professionals agreed to practice
<ul style="list-style-type: none">• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor• A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves