Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

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. Healthcare professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration

of

Midazolam 1 mg/ml solution for injection

by registered nurses with specialist endoscopy training

to induce conscious sedation before and during upper gastrointestinal endoscopy procedures

in

Powys Teaching Health Board (PTHB) endoscopy departments

Version number: PGD0146C

Reference Number: PGD 0146C
Valid from: 03/04/2026
Review Date: 03/10/2028
Expiry Date: 03/04/2029

Change history

Version number	Change details	Date
PGD0146	Initial issue	05/02/2019
PGD0146-A	Review issue including: • Update in safeguarding information • Minor wording change to unify with current template and clarification on consent process, reporting adverse events	11/03/2022
PGD0146-B	Review issue following request from service for an amendment to the maximum dose. Format update according to current PTHB template, updated safeguarding information	03/04/2023
PGD0146C	Review issue using current reference sources; title amended to match SPCs more closely. Minor changes to format to promote consistency with other PTHB PGDs. Updated safeguarding contact information. Amend reference to Xylocaine to state protocol MMP 423 Lidocaine Spray for Endoscopy. Addition of competency checklist to appendix A.	03/04/2026

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	2/23/2026
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423...	2/24/2026
Senior representative of professional group using the PGD **Paul Hooton**	Executive Director of Nursing and Midwifery for PTHB	Signed by: Paul Hooton EEABC83AC83F4B9...	2/24/2026
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	3/3/2026

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.

Appendix A provides a practitioner accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.** The final authorised copy of this PGD should be kept by PTHB for 8 years after the PGD expires. Practitioners and organisations must check that they are using the current version of the PGD.

Training and Competency of registered health professionals

[1] This includes any relevant amendments to legislation.

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with the following body: • nurses currently registered with the Nursing and Midwifery Council (NMC) Practitioners must have a current contract of employment within PTHB and be working in PTHB Endoscopy Units and fulfil the Additional requirements listed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
Initial training and knowledge requirements	• The administration of intravenous midazolam 1mg/ml solution for injection and knowledge of its uses, contraindications, and adverse effects. • Successful completion of a validated training course leading to accreditation with the Joint Advisory Group for GI Endoscopy (JAG) as a clinical endoscopist to enable the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD, i.e. in-depth knowledge of the drugs used in conscious sedation including effects, and side effects supported by supervised practice. The practitioner should undergo documented training (with regular updates) in the knowledge, skills and competencies necessary for safe sedation, to include an understanding of comorbidities that require consideration, monitoring during sedation, the recognition of the complications of sedation, and the competencies necessary to rescue patients from these complications. • Training on PTHB Gastro-Intestinal Endoscopy Operational Protocol (TEP061) • The management of patients requiring complete or partial reversal of the central sedative effects of intravenous midazolam in endoscopy with intravenous flumazenil (refer to PGD0148). NB the practitioner must also be authorised as an approved practitioner for the flumazenil PGD0148. Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines. Recommended training eLfH PGD eLearning programme. PTHB staff to access via ESR

	• must review their competency using the NICE Competency framework for healthcare professionals using patient group directions • must be familiar with the product and alert to changes in the BNF and Summary of Product Characteristics • must have undertaken training appropriate to this PGD as required by local policy, and fulfil any additional requirements defined by local policy • must have undertaken and completed Safeguarding of Children, Young People and Vulnerable Adults - Training and Competency Passport, at level applicable to the role • must have received training and be competent in the recognition, management of, and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date Intermediate Life Support (ILS) • must have access to the PGD and associated online resources **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.** **THE DECISION TO ADMINISTER ANY MEDICATION RESTS WITH THE INDIVIDUAL REGISTERED PRACTITIONER WHO MUST ABIDE BY THE PGD AND ANY ASSOCIATED ORGANISATIONAL POLICIES.**

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. • Staff must complete the eLfH PGD eLearning programme (PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • Practitioners operating under this PGD must be assessed as competent (see Appendix A) and complete a self-declaration of competence to operate under this PGD in their Personal Appraisal and Development Review (PADR). The personal development plan (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. • Evidence of training in ILS, anaphylaxis and safeguarding. • Staff must recognise their own limitations and personal accountability and act accordingly.
Ongoing training and competency	• Update at least every 2 years, or earlier in response to new local/national guidance, on the use of PGDs and midazolam solution for injection. • Annual PGD training (eLfH PGD eLearning programme)- PTHB staff to access via ESR. • Practitioners must ensure they are up to date with relevant clinical skills and management of anaphylaxis, ILS, with evidence of appropriate Continued Professional Development (CPD). • Compliance with all mandatory NHS training, including safeguarding (at level relevant to the role). • Evidence of appropriate CPD must be retained and made available on request. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this 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.**

Clinical condition

Clinical condition or situation to which this PGD applies	To provide conscious sedation before and during upper gastro-intestinal endoscopic procedures in line with endoscopy operational protocol TEP061 and British Society of Gastroenterology Guidelines. The clinical endoscopists will work under protocol TEP061 outlining the criteria for selection of individuals suitable for an endoscopic procedure in a community hospital. **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment.** **If there is any reason for concern, seek medical advice.**
Inclusion criteria	• Adults over 18 years of age, who request or require sedation prior to an upper gastro-intestinal endoscopy • Medical and drug history taken, no reason for exclusion • Individual must meet Inclusion Criteria as specified in TEP061 • Informed consent received/obtained. Refer to PTHB Consent to Treatment and Examination Policy **NB**. As part of the consent procedure for midazolam, the individual must be made aware of the potential need to use flumazenil (PGD0148) as a reversible agent for the central sedative effect of midazolam. In case of any doubt, contact medical team or emergency services. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Consider discussing with GP. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA), advice from the local Safeguarding team should be sought (see below).

Exclusion criteria (Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Individual under 18 years of age
	• Individuals in the Exclusion Criteria of TEP061
	• Known hypersensitivity to midazolam, benzodiazepines or to any of the constituents or components of the product – see SPC
	• Central nervous system depression
	• Myasthenia gravis
	• Marked neuromuscular respiratory weakness
	• Acute pulmonary insufficiency
	• Compromised airway
	• Severe respiratory failure or acute or severe respiratory depression
	• Sleep apnoea syndrome
	• Obsessional states
	• Phobic states
	• Pregnant individuals
	• Individual taking the following– refer to Drug interactions section for further detail:
	  ○ Azole antifungals
	  ○ Opioids
	  ○ HIV protease inhibitors
	  ○ CNS depressants
	  ○ Alcohol - may markedly enhance the sedative effect of midazolam
	• Individuals with acute alcoholism or with a history of alcohol or drug abuse
	• Conditions outside of the clinical situation criteria
	• No valid consent or individual/representative refuses treatment. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if individual is excluded" or "Action to be taken if individual declines treatment".

Cautions /reasons for seeking further advice from a prescriber	Special caution should be exercised when administering midazolam to high-risk individuals, who require reduced dosage and should be continuously monitored for early signs of alterations of vital functions: • Adults over 60 years of age (use is potentially inappropriate in those prone to falls (sedative, may cause reduced sensorium and impair balance)) • Chronically ill or debilitated individuals, for example with any of the following: • chronic respiratory insufficiency (NB individuals with marked neuromuscular respiratory weakness, acute pulmonary insufficiency, compromised airway, severe

	• chronic renal failure (In individuals with severe renal impairment (creatinine clearance below 30 ml/min) midazolam may be accompanied by more pronounced and prolonged sedation possibly including clinically relevant respiratory and cardiovascular depression. Midazolam should therefore be dosed carefully and titrated for the desired effect) • impaired hepatic function: Hepatic impairment reduces the clearance of IV midazolam with a subsequent increase in terminal half-life. Therefore, the clinical effects in patients with hepatic impairment may be stronger and prolonged. The required dose of midazolam may have to be reduced and proper monitoring of vital signs should be established • impaired cardiac function/ cardiac disease See dose and frequency for further details. • Individuals with personality disorders, as benzodiazepines may increase the risk of dependence and have a disinhibiting effect • Advise women to avoid breast-feeding for 24 hours after administration • Some brands may be considered high in sodium. This should be particularly taken into account for those on a low salt diet. Refer to SPC for specific product information. • Hypothermia • Hypovolaemia (risk of severe hypotension) • Vasoconstriction • Paradoxical reactions such as restlessness, agitation, irritability, involuntary movements (including tonic/clonic convulsions and muscle tremor), hyperactivity, hostility, delusion, anger, aggressiveness, anxiety, nightmares, hallucinations, psychoses, inappropriate behaviour and other adverse behavioural effects, paroxysmal excitement and assault, have been reported, these may occur with high doses and/or when the injection is given rapidly and are more prevalent in the elderly. In the event of these reactions discontinuation of the drug should be considered • Recovery may be significantly longer in the elderly, in individuals with a low cardiac output, or after repeated dosing Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. Refer to Drug Interactions section of this PGD and see BNF/SPC for full list.

	Individuals with complex multiple pathologies, polypharmacy or multiple allergies. This list is not exhaustive. Practitioners should consult the SPC for further information. Contact a prescriber where appropriate to discuss specific cautions for individuals. Ensure emergency drugs and equipment, including adrenaline, are available for the treatment of anaphylaxis and emergencies, according to local policy. Flumazenil must also be available, to reverse the effects if necessary. Personnel must be trained on administration of flumazenil and the practitioner must also be authorised as an approved practitioner for the flumazenil PGD0148. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 054 4847 Advice can also be sought from local Safeguarding Leads.

Arrangements for referral for medical advice	• Contact clinical lead for endoscopy and seek medical advice. • Record reason for referral and document advice received. • Explain reason, if possible, to individual/carer.
Action to be taken if individual excluded	• Inform appropriate medical prescriber immediately if individual is excluded from this PGD. • Record reason for exclusion and any action taken. • Explain reason to individual/carer.
Action to be taken if individual declines treatment	• Explain consequences of refusing treatment. • Offer individual alternative treatment (see protocol MMP 423 Lidocaine Spray for Endoscopy), if applicable or/and refer to another endoscopist. • Document refusal and any advice given. • Complete a 'Discharge Against Advice Form', if appropriate. • Follow local procedures as appropriate. • Call 999 as appropriate.

Details of the medicine

Name, form and strength of medicine	Midazolam 1 mg/ml solution for injection
Legal category	CD POM Schedule 3 No Reg **NB.** No requirement for safe custody – no requirement for storage in a controlled drug cabinet.
Off-label use	Medicines should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, a pharmacy professional must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be administered. Where medicines have been assessed by a pharmacy professional in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use, this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the pharmacy professional. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer that the drug is being offered in accordance with national guidance/ justified by best clinical practice, but this is outside the product license.

Route/method of administration	Midazolam 1 mg/ml solution for injection must be drawn up into a syringe by the practitioner working to the PGD, after checking each ampoule and its expiry date. Administer via slow intravenous injection through peripheral intravenous cannula using an incremental dose, titrated until the required degree of sedation is achieved- see below for dose and frequency information. The dose must be individualised and titrated and should not be administered by rapid or single bolus injection. Evaluate using comfort score and level of consciousness as per local procedure. The IV injection of midazolam should be given slowly at a rate of approximately 1 mg in 30 seconds.
Information for administration	**NB.** In clinical areas performing conscious sedation, high-strength preparations (5 mg/mL in 2 mL and 10 mL ampoules, or 2 mg/mL in 5 mL ampoules) **should not be selected** in place of the 1 mg/mL preparation. – *NHS Never Event: Mis-selection of high-strength midazolam during conscious sedation (January 2018).* • Inspect ampoule visually- should only be used if solution is clear and colourless. • Single use only, once opened the product should be used immediately, any unused solution should be discarded (in accordance with local policies). • Check expiry date of the product.

Dose and frequency	Midazolam is a potent sedative agent that requires titration and slow administration. Titration is strongly recommended to safely obtain the desired level of sedation according to the clinical need, risk factors related to the individual, physical status, age and concomitant medication.
	
	• **Adults aged 18-59 years old:**
	  ○ Initial dose: 1 mg
	  ○ Titration doses: 1 mg, if required.
	  Total dose for episode of care: 2 mg-5 mg.
	
	• **Adults aged 60-69 years old, or individuals aged 18-59 who are debilitated/chronically ill:**
	  ○ Initial dose: 0.5 mg-1 mg
	  ○ Titration doses: 0.5 mg-1 mg, if required (since in these individuals the peak effect may be reached less rapidly, additional midazolam should be titrated very slowly and carefully)

	Total dose for episode of care: do not exceed 3.5 mg.
	• **Adults aged 70 years old and over:**
	  ○ Initial dose: 0.5 mg-1 mg
	  ○ Titration doses: 0.5 mg-1 mg, if required (since in these individuals the peak effect may be reached less rapidly, additional midazolam should be titrated very slowly and carefully)
	Total dose for episode of care: do not exceed 2 mg.
	
	Doses should be administered slowly at a rate of approximately 1mg in 30 seconds.
	
	The BNF and SPC recommend that the initial dose should be administered 5-10 minutes before starting the procedure, and BSG report an onset at around 2 to 3 minutes.
	
	Follow NPSA guidance.
	
	• Single, slowly titrated dose IV prior to endoscopic procedure.
	• The onset of action is about 2 minutes after the injection (the onset of sedation may vary individually depending on the physical status of the individual and the detailed circumstances of dosing).
	• Maximum effect is obtained in about 5 to 10 minutes.

Quantity to be administered	See dose and frequency section above
Maximum or minimum treatment period	Single, slowly titrated dose. This dosage schedule may only be administered once within a 6-week period.
Storage	Stock must be securely stored according to PTHB Medicines policy (MMP 001) and in conditions in line with SPC. Store in the original package to protect from light. Do not store above 25°C.

Drug interactions	This list is not exhaustive. Refer to BNF and SPC for full list. NB some drug interactions are exclusions – seek advice from a prescriber if required. Midazolam elimination may be altered in individuals receiving compounds that inhibit or induce CYP3A4 and the dose of midazolam may need to be adjusted accordingly. Midazolam is metabolized by CYP3A4 and CYP3A5. After a single dose of IV midazolam, the impact on the maximal clinical effect due to CYP3A4 inhibition will be minor while the duration of effect may be prolonged. • Azole antifungals (for example ketoconazole, voriconazole, fluconazole, isavuconazole, itraconazole and posaconazole) increase the plasma concentration of midazolam -NB see exclusion criteria • HIV Protease inhibitors (eg. atazanavir, darunavir, fosampenavir, lopinavir, ritonavir) increase midazolam plasma concentration –NB see exclusion criteria • CNS depressants are likely to increase clinical effects of midazolam, enhancing sedation (possibly including severe sedation that could result in coma or death) and potentially causing respiratory depression- see exclusion criteria. The BNF lists medicines that have effects on the CNS and can cause sedation. In some cases, use of two or more drugs that have effects on the CNS might also increase the risk of CNS depressant effects (which could range from sedation to unconsciousness, coma, respiratory depression, and/or cardiovascular depression). Access BNF online to check this list- see exclusion criteria • Opioids- midazolam taken with opioids can produce additive CNS depressant effects, thereby increasing the risk of sedation, respiratory depression, coma and death – see exclusion criteria • Alcohol - may markedly enhance the sedative effect of midazolam. Alcohol intake should be strongly avoided in case of midazolam administration. The concomitant use of midazolam with alcohol and/or CNS depressants should be avoided. Such concomitant use has the potential to increase the clinical effects of midazolam possibly including severe sedation that could result in coma or death, or clinically relevant respiratory depression – see exclusion criteria

	• Apalutamide is predicted to decrease the exposure to Midazolam. Manufacturer advises monitor and adjust dose
	• Atorvastatin may increase plasma concentrations of IV midazolam
	• Berotralstat is predicted to increase the exposure to Midazolam. Manufacturer advises monitor adverse effects and adjust dose
	• Calcium-channel blockers (diltiazem and verapamil are predicted to increase the exposure to Midazolam. Manufacturer advises monitor adverse effects and adjust dose)
	• Clobazam and efavirenz are weak inducers of midazolam metabolism
	• Clozapine might increase the risk of respiratory depression and circulatory collapse when given with Midazolam. See exclusions above regarding CNS depressants
	• Cobicistat is predicted to markedly to very markedly increase the exposure to midazolam. Manufacturer advises avoid concomitant use or adjust dose
	• Dronedarone is predicted to increase exposure to midazolam. Manufacturer advises monitor adverse effects and adjust dose
	• Hepatitis C virus (HCV) protease inhibitors reduce midazolam clearance
	• Ivosidenib is predicted to decrease the exposure to Midazolam. Manufacturer advises monitor and adjust dose
	• Letermovir is predicted to increase exposure to midazolam. Manufacturer advises monitor adverse effects and adjust dose
	• Lumacaftor is predicted to decrease the exposure to Midazolam. Manufacturer advises monitor and adjust dose
	• Macrolide antibiotics increase midazolam plasma concentration. For example:
	  ○ Erythromycin- manufacturer advises monitor adverse effects and adjust dose
	  ○ Clarithromycin- manufacturer advises avoid or adjust dose
	• NK1 receptor antagonists may increase the exposure to midazolam. For example:
	  ○ Aprepitant- manufacturer advises monitor adverse effects and adjust dose
	  ○ Fosaprepitant- manufacturer advises caution

	○ Netupitant- manufacturer advises monitor adverse effects and adjust dose • Phenobarbital is predicted to decrease the exposure to Midazolam. See exclusions above regarding CNS depressants • Primidone is predicted to decrease the exposure to Midazolam. See exclusions above regarding CNS depressants • Protein kinase inhibitors may increase the exposure to midazolam, for example: ○ Ceritinib- manufacturer advises avoid or adjust dose ○ Crizotinib- manufacturer advises monitor adverse effects and adjust dose ○ Fedratinib- manufacturer advises monitor adverse effects and adjust dose ○ Idelalisib- manufacturer advises avoid or adjust dose ○ Imatinib- manufacturer advises monitor adverse effects and adjust dose ○ Nilotinib- manufacturer advises monitor adverse effects and adjust dose ○ Tucatinib- manufacturer advises avoid or adjust dose • Protein kinase inhibitors predicted to decrease the exposure to midazolam include: ○ Encorafenib- manufacturer advises monitor and adjust dose • Quercetin (also contained in ginkgo biloba) and panax ginseng both have weak enzyme inducing effects and potentially reduce exposure to midazolam • Rucaparib slightly increases the exposure to Midazolam. Manufacturer advises monitor and adjust dose • Sedative/hypnotic agents- individuals taking other sedative/hypnotic agents are likely to experience enhanced sedation and respiratory depression • St John's Wort may reduce plasma concentrations of midazolam • Ticagrelor has only small effects on intravenously administered midazolam exposure • Vemurafenib modulates CYP isozymes and induces CYP3A4 mildly which may result in a decrease of midazolam exposure • Rifampicin and carbamazepine may decrease the plasma concentrations of midazolam. Manufacturer advises monitor and adjust dose

	• Phenytoin and fosphenytoin may decrease the plasma concentrations of midazolam. See exclusions above regarding CNS depressants • Mitotane or enzalutamide may result in a decrease of midazolam levels. Manufacturer advises monitor and adjust dose Refer to a prescriber if any concern of a clinically significant drug interaction and document advice given.

Adverse effects	Common or very common side effects: • Alertness decreased • Anxiety • Ataxia (more common in elderly) • Confusion (more common in elderly) • Depression • Dizziness • Drowsiness • Dysarthria • Fatigue • Headache • Hypotension • Mood altered • Muscle weakness • Nausea and vomiting • Respiratory depression (particularly with high dose and intravenous use—facilities for its treatment are essential) • Sleep disorders • Tremor • Vision disorders • Withdrawal syndrome This list is not exhaustive. Refer to BNF or SPC for complete list. Higher doses are associated with prolonged sedation and risk of hypoventilation. The co-administration of midazolam with other sedative, hypnotic, or CNS-depressant drugs results in increased sedation. Midazolam accumulates in adipose tissue, which can significantly prolong sedation, especially in individuals with obesity, hepatic impairment or renal impairment. Severe cardiorespiratory adverse events including respiratory depression, apnoea, respiratory arrest and/or cardiac arrest have been reported- these are more likely to occur when the injection is given too rapidly or when a high dosage is administered. Procedures for dealing with adverse reactions to treatment provided: • Follow ILS and relevant endoscopy protocols • Stop the procedure and assess nature of event – ensure adequate oxygenation and ventilation. • If necessary, remove endoscope.

	• Consider administration of the antagonist flumazenil (see PGD for Flumazenil PGD0148) and assess. • If necessary, commence life support and call for assistance. • Ensure records are kept in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Record via Once for Wales Reporting System if adverse reaction is significant (refer to local organisational policy and see below). If serious adverse effects are noted, complete a Yellow Card (found in the BNF) or submit online through the MHRA website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use. Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone must be available for immediate use. In case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD 0017 and anaphylaxis procedure • Request medical assistance urgently. If assistance is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in individual's notes • Ensure all individual's records are marked **ALLERGIC TO MIDAZOLAM** (and state brand). • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers All significant adverse drug reactions and any administration errors must be recorded via Once for Wales Reporting System.

Special considerations / additional information	Ensure there is immediate access to resuscitation equipment including adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone. Flumazenil must also be available. Midazolam should be administered in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function and by persons specifically trained in the recognition and management of expected adverse events including respiratory and cardiac resuscitation. Guidelines commissioned by the British Society of Gastroenterology (BSG) recommend supplemental oxygen where any level of sedation is used.
Records to be kept	The following must be recorded in line with local procedures for recording clinical records (all treatment will be recorded on the standard PTHB endoscopy reporting form and nursing documentation, a copy of which will be held in the individual's medical records and a further copy forwarded to the individual's GP): • That valid informed patient consent to treatment was obtained or a decision to treat was made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent, if appropriate. • Patient inclusion or exclusion from PGD • Name, date of birth and address of individual • Name and address of GP with whom the individual is registered • Examination finding/s, where relevant • Any medical and drug history taken, including any known allergies/adverse events and nature of reaction (if established) • Any reasons for exclusion or referral, any advice received from medical team, if applicable, actions taken, and advice given to individual/ carer • Name of medication administered, manufacturer, batch number(s) and expiry date(s) • Date and time of administration • Detail anatomical site of administration, route, dose, volume, and strength of midazolam administered • Name and signature of registered health professional responsible for administration

	• Any advice given • Details of any adverse reactions and actions taken • Record that medication was administered via PGD, record title and version number Records should be signed and dated and securely kept for a defined period in line with local policy. 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. **If the individual required the use of flumazenil to reverse the effects of sedation, it is defined as an Endoscopy Adverse Event – refer to TEP061. The Chief Pharmacist and Medical Director must be notified by email within 24 hours when it has been necessary to use flumazenil to reverse conscious sedation (email: info.medicinesmanagement.powys@wales.nhs.uk).**

Patient information

Written/verbal information to be given to individual or carer	• PTHB Upper endoscopy patient information leaflet and Endoscopy discharge leaflet following sedation. • Individuals should be informed of the signs and symptoms of respiratory depression and sedation and advised to seek urgent medical attention should these occur. • Advise individual to avoid alcohol for at least 24 hours after administration of midazolam. If insufficient sleep occurs or alcohol is consumed, the likelihood of impaired alertness may be increased. • Advise women to avoid breast-feeding for 24 hours after administration. • Midazolam has a major influence on the ability to drive or perform skilled tasks and use machines. Avoid driving, operating machinery, signing legal documents until completely recovered- the risk extends to at least 24 hours after administration. • Give appropriate advice according to "Guidance for healthcare professionals on drug driving". Stress that it is an offence to drive while under the influence of this medicine, unless they know it does NOT affect their ability to drive safely.

	• Anterograde amnesia may occur with therapeutic doses, the duration of which is directly related to the administered dose, with the risk increasing at higher dosages. Prolonged amnesia can present problems in outpatients, who are scheduled for discharge following intervention. After receiving midazolam parenterally, individuals should be discharged from hospital or consulting room only if accompanied by an attendant. The relative/carer must be advised to stay with the individual for 12 hours post procedure.
	• Inform individual of possible side effects and their management.
	  ○ Advise individual/carer to contact GP/NHS 111 out of hours if side effects noted
	  ○ Advise individual/carer to contact the endoscopy unit in working hours
	• All individuals are to be given written discharge instructions including relevant contact numbers (endoscopy unit during working hours, GP/NHS 111 outside of those hours).

Follow-up advice to be given to individual or carer	• Follow PTHB discharge procedures. • Advise individual to seek medical advice immediately if they have any unexpected reaction or other cause for concern. Contact GP via surgery or emergency on call service or NHS 111

Key references

1. British National Formulary Midazolam – accessed online 25/09/25
2. Endoscopy Operational Policy TEP 061, May 2024, PTHB
3. Summary of Product Characteristics:

   Midazolam 1mg/1ml solution for injection/infusion A S Kalceks 05/01/2024

   Midazolam 1mg/ml Injection Martindale Pharma Updated 05 Oct 2023
   Midazolam 1mg/ml solution for injection/ infusion Hameln pharma ltd updated 07/09/2023
4. Patient information leaflet:

   Midazolam 1mg/1ml solution for injection/infusion A S Kalceks revised 10/2024

   Midazolam 1mg/ml Injection Martindale Pharma revised April 2025

   Midazolam 1mg/ml solution for injection/infusion. Hameln revised 03/2024
5. NPSA/2008/RRR011- Reducing risk of overdose with midazolam injection in adults
6. Guideline for obtaining valid consent for gastrointestinal endoscopy procedures; Everett SM, et al. Gut 2016;0:1–17.
7. AOMRC safe sedation practice for healthcare procedures An update; February 2021

Appendix A. Staff accredited to use this Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the PGD to work under it.
The authorising manager must use the competency checklist (below).

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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.

Printed name of registered health professional	Signature of registered health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB for 8 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N)	Comments (also specify any further training required)
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.