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Health Board

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

This protocol 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 protocol should be used. Healthcare professionals should always access the protocol via the Powys Teaching Health Board (PTHB) internet to ensure that they are always working to the most up to date version

**Protocol for the administration of Pharmacy (P) classified
Chlorhexidine with Lidocaine Gel (Instillagel®) prior to Indwelling
Urinary Catheterisation in individuals over the age of 16 years
in PTHB wards, departments and MIU**

by a competent, registered **Health Care Professional** working in PTHB.

This protocol is integral to PTHB/[GNP 003](#) Urinary Catheter Management
Standard Operating Procedure (SOP) and is applicable only in conjunction with
full practitioner adherence to the [GNP 003](#) SOP

Document Reference No:	PTHB / MMP 486	
Version No:	1	
Issue Date:	07/10/2026	
Expiry Date:	06/10/2029	
Author:	Specialist Continence Service Lead and Medicines Management Pharmacist	
Document Owner:	Chief Pharmacist	
Accountable Executive:	Executive Medical Director	
Approved By:	Local signatories (see p.3)	
Approval Date:	07/10/2026	
Document Type:	Protocol	Clinical
Scope:	Authorised competent, registered Health Care Professional in PTHB wards, departments and MIU	

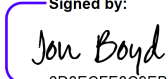
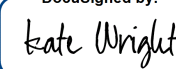
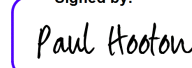
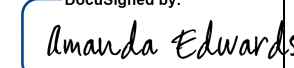
Do not print this document. The latest version will be accessible via the internet. If the expiry date has passed, please contact the Author for advice.

Change history

Version number	Change details	Date
MMP 486	Initial Issue	07/10/2026

For advice on protocol use in practice/advised supporting governance please refer to [When not to use a PGD](#).

Protocol authorisation

Name	Job title and organisation	Signature	Date
Chief Pharmacist Jonathan Boyd	Chief Pharmacist for PTHB	Signed by:  6D8ECFE8C9EB423...	10/6/2026
Senior doctor Dr Kate Wright	Lead doctor for PTHB	DocuSigned by:  1F267952823F473...	10/13/2026
Senior representative of professional group using the protocol Paul Hooton	Executive Director of Nursing and Midwifery for PTHB	Signed by:  EEABC83AC83F4B9...	10/6/2026
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by:  74A4E51A42E9473...	10/14/2026

Appendix A provides a Staff Permitted to use protocol accreditation sheet. Individual practitioners must be authorised by name to work to this protocol.

The final authorised copy of this protocol should be kept by PTHB for 25 years after the protocol expires.

Training and competency of registered health professionals

Qualifications and professional registration	Practitioners must only work under this protocol where they are competent to do so having attained competency as outlined in GNP 003: Urinary Catheter Management Standard Operating Procedure (SOP) pathway to practice. Practitioners working under this protocol must be a registered healthcare professional with a current contract of employment with PTHB and must adhere to their appropriate professional code of conduct and the RCN/RPS Professional Guidance on the Administration of Medicines (2019). Practitioners must also fulfil the training and Additional requirements listed below. Check Appendix A – Staff permitted to use the protocol accreditation sheet to confirm whether the registered practitioner has organisational authorisation to work under this protocol.
Initial training	• Be familiar with GNP 003 Urinary Catheter Management SOP which includes obtaining consent, safeguarding, product selection, procedure and documentation. • Complete actions and achieve practical and theoretical competence under GNP 003 Urinary Catheter Management SOP Pathway to Practice which is the organisations standard for knowledge and clinical judgement to use this protocol in practice to complete indwelling catheterisation. • Must be familiar with the administration of Chlorhexidine with Lidocaine gel (Instillagel®) prior to indwelling urinary catheterisation and knowledge of its actions, contraindications and adverse effects and alert to changes in the BNF/ Summary of Product Characteristics. • Must have undertaken appropriate training for working under protocols for administration of medicines (Team leaders may access 'Protocol and guideline awareness training' by sending a request to info.medicinesmanagement.powys@wales.nhs.uk and will be accountable for training their team). • Must work within PTHB guidelines, PGDs/protocols, SOPs and departmental policies that they have been accredited to work to. • Must have current competence in assessing capacity and follow Mental Health Capacity Act 2005 guidance relating to consent to treatment.

	• Must have undertaken and completed at least level 2 Safeguarding of Children, Young people and Vulnerable adults – Training and Competency passport, as applicable to the role • Must be competent in the recognition, management and reporting of recognised adverse reactions, with up to date Basic Life Support skills (BLS)(as a minimum). Must be competent in reporting via the MHRA Yellow card scheme and via Once for Wales Reporting System. • The practitioner must either be competent in the management of anaphylaxis, or they must ensure there is someone who is anaphylaxis trained and competent in the administration of adrenaline 1 in 1000 immediately available. • Must have access to the protocol and associated online resources. The practitioner must be authorised by name as an approved practitioner under the current version of this protocol before working to it.
Competency assessment	Individuals operating under this protocol do so in conjunction with attainment of GNP 003 Urinary Catheter Management SOP Pathway to Practice, which is recorded on ESR, renewed every 3 years and forming part of the individual's annual PADR. Individuals operating under this protocol must have also been assessed as competent to work to this protocol- this should be recorded using the competency checklist in Appendix A. Practitioners must make a self-declaration of competency to work to this protocol 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 annual protocol training. Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. ESR records of mandatory NHS training, including a minimum of level 2 Safeguarding of Children, Young People and Vulnerable Adults, up to date BLS skills (as a minimum) and management of anaphylaxis, including the administration of adrenaline (if applicable).

Ongoing training and competency	The Pathway to Practice within GNP 003 Urinary Catheter Management SOP to perform urinary catheterisation is renewed every 3 years alongside ESR mandatory training for a minimum of safeguarding level 2 and annual BLS. The practitioner must either be competent in the management of anaphylaxis, or they must ensure there is someone immediately available who is competent in the administration of adrenaline 1 in 1000. Practitioners must ensure they have evidence of appropriate Continued Professional Development (CPD), which must be retained and made available on request. Practitioners must update at least every year (or earlier in response to new local/national guidance), on the use of protocols and Chlorhexidine with Lidocaine gel (Instillagel®) during urinary catheterisation. Practitioners should be constantly alert to any sources of medicines information. It is the responsibility of the healthcare professional to maintain their own competency to practice within this protocol and to ensure they remain up to date with the use of the medicine included in the protocol. Identified training needs should be discussed with the individual's line manager.
The decision to administer any medication rests with the individual registered practitioner who must abide by the protocol and any associated organisation policies.	

Clinical condition	
Clinical condition or situation to which this protocol applies	Inpatients, patients in PTHB departments, and attendees in MIU who are assessed under the inclusion criteria of GNP 003 Urinary Catheter Management SOP as requiring insertion of an indwelling urinary catheter. 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. These tasks cannot be delegated and so the registered healthcare professional making the decision to administer a medicine under this protocol must carry out the administration to the individual.
Inclusion criteria	• Individual has been assessed using GNP 003 Urinary Catheter Management SOP as requiring indwelling urinary catheterisation and meets the specific inclusion criteria including safeguarding (Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults (POVA)), advice from the local Safeguarding team should be sought (see below)) • Informed consent obtained. Refer to GNP 003 Urinary Catheter Management SOP and PTHB Consent to Treatment and Examination Policy. Individual has been fully counselled regarding the procedure, consent documented, and individual informed that they are being treated within a protocol • A medical and drug history has been taken and documented and no contra indications/reasons for exclusion have been identified • Individual is over the age of 16 In case of any doubt, contact medical team.

Exclusion criteria	• Conditions outside of the clinical situations criteria, or where individual does not meet the inclusion criteria under the specific male, female, suprapubic sections of GNP 003 Urinary Catheter Management SOP • Refer to GNP 003 Urinary Catheter Management SOP for specific exclusion criteria • 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 section "Action if individual declines". • Individual is under 16 years of age. • Pregnancy, during labour and immediately post-partum. • Individuals with known or suspected allergy or hypersensitivity to lidocaine, amide-type anaesthetics, to chlorhexidine, alkyl hydroxybenzoates, or to any excipients in the formulation – see SPC for details. • Instillagel® should not be used in individuals who have damaged or bleeding mucous membranes because of the risk of systemic absorption of the lidocaine hydrochloride. Refer to section "Action if individual excluded"
Cautions /reasons for seeking further advice from a prescriber	• Medication containing Lidocaine should be used with caution in individuals receiving antiarrhythmic drugs. • Products containing local anaesthetics should be used with caution in individuals with impaired cardiac conditions, hepatic insufficiency, liver failure or cirrhosis, and in epileptics. • Instillagel® contains: ○ Methyl hydroxybenzoate and propyl hydroxybenzoate (parabens) which may cause allergic reactions (possible delayed) ○ Propylene glycol which may cause skin irritation. Please see SPC for other ingredients. • Instillagel® must not come into contact with the eye due to the risk of visual damage. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution

	beyond the intended area. Extreme care must be taken during application to ensure that Instillagel® does not migrate beyond its intended application site and into the eyes. If Instillagel® comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought. Seek medical advice and document advice given and action taken. Refer to BNF/SPC for full list of cautions. 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 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 0544847 Advice can also be sought from local Safeguarding leads.
Arrangements for referral for medical advice	Contact ward doctor, GP via the surgery or the emergency on-call service and document advice given.
Action if individual excluded	Explain reason to the individual; record reason and any advice received/given. For individuals who do not meet the criteria for use of Instillagel® or where an allergy exists, consider the use of a plain lubricant -refer to GNP 003 Urinary Catheter Management SOP. If necessary, refer to a doctor, prescriber or continence service.
Action if individual declines	The patient information leaflet should be available to inform consent.

	Explain consequences of refusing treatment, document refusal and any advice given. Offer an alternative option if appropriate or refer to a doctor, prescriber or continence service.
Details of the medicine	
Name, form and strength of medicine	Instillagel® Gel (active ingredients chlorhexidine gluconate 500microgram per 1ml, lidocaine hydrochloride 20mg per 1ml)
Legal Category	P Pharmacy
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 the local Medicines Management team must be consulted. Where medicines have been assessed by Medicines Management in accordance with national or specific product recommendations as appropriate for continued use, this would constitute off-label administration under this protocol. The responsibility for the decision to release the affected medicines for use lies with Medicines Management.
Route/Method of Administration	Via urethra or suprapubic site Refer to GNP 003 Urinary Catheter Management SOP for guidance
Dose and Frequency	6ml for anatomically female urinary tract 11ml for anatomically male urinary tract 6ml for a suprapubic catheter change Single dose given prior to catheter insertion allowing time to take effect as per manufacturers guidance
Storage	Medicines must be securely stored according to PTHB MMP 001 medicines policy and in conditions specified in the individual SPC. This product is for single use only. The syringe and any unused gel must be discarded.

	If the seal is broken the product should be discarded. Do not use after the expiry date stated (the expiry date refers to the last day of that month).
Drug Interactions	Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic medications. Medication containing Lidocaine should be used with caution in individuals receiving antiarrhythmic drugs. NB. Refer to BNF/SPC for full list of potential interactions. Refer for medical advice as appropriate and document advice given.
Identification, management, and reporting of adverse reactions	Undesirable effects of the local anaesthetic, lidocaine, are possible where there is severe injury to the mucosa at the site of administration and absorption may occur. Examples are anaphylaxis, fall in blood pressure, bradycardia or convulsions. Instillagel® may cause drowsiness. In the event of excessive absorption of lidocaine into the bloodstream, symptoms may include CNS effects (such as convulsions, unconsciousness and possible respiratory arrest) and cardiovascular reactions (such as hypotension, myocardial depression, bradycardia and possibly cardiac arrest). Frequency of potential eye disorders following accidental exposure unknown: Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment. Instillagel contains methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions (possible delayed). It also contains propylene glycol which may cause skin irritation. This list is not comprehensive - a detailed list of adverse reactions is available in the BNF and the product's SPC.

	Possible side effects include serious allergic reaction that might cause difficulty with breathing or dizziness (anaphylaxis). In the case of an acute anaphylactic reaction occurring, someone who is anaphylaxis trained and competent in the administration of adrenaline must be immediately available. 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) PGD0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP 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 Chlorhexidine with Lidocaine gel (Instillagel®) • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system Any adverse reaction must be documented in the individual's medical records and their doctor/ GP informed. Healthcare professionals and individuals/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 or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults that may be attributable to the medication should be reported. All suspected adverse reactions in children that may be attributable to the medication should be reported. All significant adverse drug reactions, any administration errors or untoward incidents will be reported via Datix Once for Wales Reporting system and monitored via incident reports.
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Records to be kept	Administration of Instillagel® must be clearly recorded on the individual's medication record. Record consultation details as required by local procedures- the following must be included: • Reason allowing individual to be treated under this protocol • That valid informed 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 • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical history, including medication history, known allergies or previous adverse events and nature of reaction • Any reasons for exclusion or referral, including actions taken • Any safeguarding concerns and appropriate actions taken • Printed name and signature of registered health professional responsible for administration • Date and time of administration • Name, form, route, strength and dose of drug administered • Expiry date • Details of any adverse reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any advice received from medical cover and advice given to individual/carer • Record that medication was administered via a protocol, record protocol number and letter indicating the version Records should be signed and securely kept for a defined period in line with local policy. All records should be clear, legible, factual and contemporaneous. Ensure the electronic records (eg. WNCR, WCCIS, RIO) covers all elements of legal processes for an indwelling urinary catheterisation. Complete Catheter Passport where applicable.
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	A record of all individuals receiving treatment under this protocol should be kept for audit purposes in accordance with local policy. The head of department/ward manager must arrange an annual retrospective audit of a minimum of 5 records over a 12-month period. This audit should sample 10% of individuals who have been treated according to this protocol in each location where the protocol has been used, to monitor compliance. The records must be reviewed for rationale for administering the product, checking this was in accordance with the protocol, that clear documentation is in place and that the competency checklist has been completed as part of authorisation of individuals to work to this protocol. The results should be available for review by the medicines management team upon request.
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Patient information

Written/verbal information to be given to individual or carer	• Explain indication, contraindications, cautions and potential side effects, as documented in the patient information leaflet (PIL). • Provide PIL. • Inform individual that they are being treated within a protocol. • Inform individual that the ability to drive and operate machinery may be slightly impaired after the use of Instillagel®. If affected, individuals should be advised not to drive or use machinery.
Follow-up advice to be given to individual or carer	• Confirm individual's understanding of potential side effects from Instillagel® and actions to take if these occur. • Signpost individual to appropriate professional for advice after procedure. • 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.

Key References

- [British National Formulary \(BNF\)](#) - accessed 12/08/2026
- MHRA. [Product Datasheet: Instillagel®](#) Farco-Pharma GmbH. <https://products.mhra.gov.uk>. Last revised 18/12/2024.
- MHRA. [Instillagel package leaflet](#), last revised January 2025
- Royal Pharmaceutical Society: Professional Guidance on the Administration of Medicines in Healthcare settings (2019)
- Specialist Pharmacy Service [When not to use a PGD](#) updated 01/04/2026
- [All medical devices and medicinal products containing chlorhexidine - Risk of anaphylactic reaction due to chlorhexidine allergy \(Various manufacturers\) \(MDA/2012/075\)](#)
- [GNP 003](#) Urinary Catheter Management SOP, 5th May 2026

Appendix A Staff Permitted to use the protocol accreditation sheet

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this protocol. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professional below who has signed the protocol to work under it.

The authorising manager must use the competency checklist (below).

Practitioner: By signing this protocol you are indicating that you agree to its contents and that you will work within it. Protocols 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 protocol 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 (Authorising Manager)	Signature of senior representative authorising health professional (Authorising Manager)	Date

The authorising manager should retain a copy of the list, which will be required for audit purposes. This list should be kept by PTHB for 25 years after the protocol 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 protocol.

Review of authorisation will take place on each protocol update and at the individual's annual PADR.

Name: Role:		Sign / Initial	Further training identified (Y/N)	Comments
1	The protocol sign off is for the following protocol:(document the exact title and protocol number) _____			
2	We have discussed the expiry of the protocol and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the protocol			
4	The protocol has been read in full by the staff member			
5	The identified training has been completed as specified in the protocol 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, to the staff member, in conjunction with the protocol Appendix A staff accreditation sheet. A copy of this form should also be kept by service lead in the training file.