Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board
Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Protocol 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 Protocol should be used. Health professionals should always access the Protocol via the 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®) during

Intrauterine Contraception insertion

by **Registered Nurses or Midwives**

working in Powys Teaching Health Board **Sexual Health Service.**

Version number: MMP200

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

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys
Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Change history

Version number	Change details	Date
MMP200	Initial Issue to replace PTHB / WCH 061	16/08/2023

For advice on protocol use in practice/advised supporting governance please refer to When Patient Group Directions are not required.

Protocol authorisation

Name	Job title and organisation	Signature	Date
Chief Pharmacist Jacqueline Seaton	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	8/24/2023

Appendix A provides a Staff Permitted to use Protocol Signature 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.

Competencies of registered health professionals working under the Protocol	
Qualifications and professional registration	Practitioners must only work under this Protocol where they are competent to do so. Practitioners working under this Protocol must also be a registered professional with the following body: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) Current contract of employment with Powys Teaching Health Board (PTHB), providing Sexual Health Services and holding a Letter of Competence in Intrauterine Techniques (LoC IUT). The practitioners must also fulfil the training and additional requirements detailed below. Check Appendix A: Staff permitted to use the Protocol.
Initial training	• The administration of Chlorhexidine with Lidocaine (Instillagel®) during Intrauterine Contraception insertion (Refer to PGD 0160 for the administration of levonorgestrel releasing intrauterine system (LNG-IUD) where appropriate or the CU-IUD SOP) and knowledge of its actions, uses, contraindications and adverse effects. • Be alert to changes in the BNF/ Summary of Product Characteristics • Must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in reporting via the MHRA Yellow card scheme and via Once for Wales Reporting System. • Must be competent in the administration of adrenaline and have up to date Basic Life Support skills. Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this Protocol before working to it. • must complete Protocol awareness training. • must have access to the Protocol and associated online resources. • must have undertaken and completed at least level 2 Safeguarding of Children, Young people and Vulnerable adults – Training and Competency passport.

	• must have current competence in assessing capacity and follow Mental Health Capacity Act guidance relating to consent to treatment. • must work within PTHB guidelines, PGDs/protocols, SOPs and departmental policies that they have been accredited to work to. **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PROTOCOL BEFORE WORKING ACCORDING TO IT.**
Competency assessment	Evidence of ongoing Protocol awareness training to be submitted to Line Manager annually. Letter of Competence in Intrauterine Techniques (LoC IUT). ESR evidence of annual training in Management of anaphylaxis, including the administration of adrenaline. ESR evidence of up to date BLS skills. ESR evidence of a minimum of level 2 Safeguarding of Children, Young People and Vulnerable Adults. Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Practitioners must make a self-declaration of competency on PADR.
Ongoing training and competency	Updating at least every 2 years on the use of Protocols and Chlorhexidine with Lidocaine (Instillagel®) during Intrauterine Contraception insertion. Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis including the administration of adrenaline, Basic Life Support Skills, with evidence of appropriate Continued Professional Development (CPD). Valid Letter of Competence in Intrauterine Techniques (LoC IUT) (refer to FSRH LoC IUT Training).

	Compliance with all mandatory NHS training including a minimum of safeguarding level 2. Practitioners should be constantly alert to any sources of medicines information. Must adhere to their professional code of conduct and the Royal Pharmaceutical Society Professional Guidance on the Administration of Medicines (2019). **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 medicines included in the protocol. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the protocol and further training provided as required.**

Clinical condition or situation to which this Protocol applies	
Clinical condition or situation	Female with childbearing potential who requests an intrauterine device as a method of contraception or as a method of emergency contraception and requires the use of topical anaesthetic gel to aid insertion. For use in conjunction with PTHB PGDs or the CU-IUD SOP as necessary. **It is the responsibility of the administering healthcare professional to ensure that the patient 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 nurse/ midwife making the decision to administer a medicine under this protocol must carry out the administration to the client.**
Inclusion criteria	• Informed consent obtained. Refer to PTHB Consent to Treatment and Examination Policy. Client has

	been fully counselled regarding the procedure and consent form completed. • Planned insertion of an intrauterine contraceptive device. • A full clinical history (including medical and drug history) has been taken and is documented on the Powys Teaching Health Board Sexual Health Service IUD (Cu-IUD)/LNG-IUD checklist (Appendix B) and no contra indications/ reasons for exclusion have been identified. • Client is 13 to 55 years of age. • If the client is known or believed to be less than 16 years of age, competence has been assessed based on Fraser Guidelines and documented accordingly. • For all clients aged 13 to 17 years a CESERQ 4/15 must be completed. If any safeguarding concerns or significant risk factors are identified, then a safeguarding referral to Powys Children's Services must be raised and PTHB safeguarding procedures followed. Advice can be sought from PTHB Safeguarding Team. In case of any doubt, contact medical team.

Exclusion criteria (Exclusion under this Protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations 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 sections "Action to be taken if client is excluded" or "Action to be taken if client declines treatment". • Contraindications identified via the Powys Teaching Health Board Sexual Health Service IUD (Cu-IUD)/LNG-IUD checklist (Appendix B). • Client is aged under 13 years old. Any child suspected of engaging in sexual activity under the age of 13 must be referred to Powys Children Services. The Safeguarding Procedures must be followed - advice can be sought from PTHB Safeguarding Team. • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines, or any individual who has been assessed as not having the capacity to understand the nature and purpose of the treatment. • Clients who do not agree to share the relevant clinical information. • Current known or suspected pregnancy. • Known or suspected allergy or hypersensitivity to 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.

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 also be used with caution in individuals with impaired cardiac conditions, hepatic insufficiency and in epileptics.
	• Instillagel® contains:
	  ○ Methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions (possible delayed)
	  ○ Propylene glycol which may cause skin irritation.

	○ Please see SPC for other ingredients. 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 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 0544847 Advice can also be sought from local Safeguarding leads.
Arrangements for referral for medical advice	Refer to a GP, gynaecologist, or a level 3 specialist sexual health service as soon as possible
Action if individual excluded	Explain reason to the individual. Record reason and any advice given. Those clients who do not meet the criteria for use of Instillagel® and where Intrauterine contraception cannot be fitted without its use should be referred to a level three specialist sexual health service as soon as possible. Condoms or an alternative suitable method of contraception should be provided. If a child under 13 years of age is known to have engaged in sexual activity this must be referred to Powys Children Service and the PTHB Safeguarding Team notified. See Cautions section for further details.

Action if individual declines	Explain consequences of refusing treatment. Document refusal and any advice given. Where Intrauterine contraception cannot be fitted without its use, the individual should be referred to a level three specialist sexual health service as soon as possible. Condoms or an alternative suitable method of contraception should be provided.
Description of Treatment	
Name, form and strength of medicine	**Instillagel® Gel** (active ingredients chlorhexidine digluconate solution 500microgram per 1ml, lidocaine hydrochloride 20mg per 1ml)
Legal Category	P Pharmacy
Route/Method of Administration	Endocervical
Dose and Frequency	Maximum 6ml to be applied endocervical. This protocol allows a single dose to be administered.
Storage	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.
Drug Interactions	Medication containing Lidocaine should be used with caution in individuals receiving antiarrhythmic drugs. Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic medications. **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 and absorption may occur. Examples are anaphylaxis, fall in blood pressure, bradycardia or convulsions. 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). This list is not comprehensive - refer to the BNF / SPC for a comprehensive list of adverse drug reactions. Any adverse reaction must be documented in the clients' medical records and the doctor/ GP informed. 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. 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. In the case of an acute reaction occurring, 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 policy • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in clients' notes

	• Ensure all client records are marked **ALLERGIC TO Chlorhexidine with Lidocaine (Instillagel®)** • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers All significant adverse drug reactions should be reported via Once for Wales Reporting System.

Records to be kept	Record consultation details as required by local procedures. Administration of any medication must be clearly recorded on the Powys Teaching Health Board Sexual Health Service IUD (Cu-IUD)/LNG-IUD checklist (Appendix B) or the patients sexual health records, which should be stored in the medical records. All safeguarding concerns and appropriate actions should be clearly documented in the notes section of Appendix B. The following must be included: • Reason allowing individual to be treated under this protocol. • Relevant past and present medical history, including medication history. • Any known allergies or previous adverse events and nature of reaction. • 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. Where the client is under 16 years of age Fraser competency must be documented in the medical records. • Name of individual, address, date of birth. • GP contact details where appropriate. • Any reasons for exclusion or referral, including actions taken. • Examination finding/s where relevant. • Printed name and signature of registered health professional responsible for administration. • For administration, record: o Date and time of administration o Name, form, strength and dose of drug administered o Route of administration o Expiry date(s) and batch number • Details of any adverse reactions and actions taken should be clearly documented in the notes section of Appendix B.

	• 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 client/carer. • Record that medication was administered via a protocol, record protocol title and version number • If the client is 13-17 years the CSERQ 4/15 should be completed 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. A record of all individuals receiving treatment under this Protocol should be kept for audit purposes in accordance with local policy.

Client information	
Written/verbal information to be given to individual or carer	• Provide patient information leaflet. • Inform client that they are being treated within a protocol • The ability to drive and operate machinery may be slightly impaired due to the use of Instillagel®. If affected, clients should be advised not to drive or use machinery.
Follow-up advice to be given to individual or carer	Inform individual of possible side effects and their management. Where appropriate, advise follow up with Sexual Health Service. Advise them 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.

References.

- BNF online edition; accessed 16/06/23
- MHRA. Product Datasheet: Instillagel® Farco-Pharma GmbH. https://products.mhra.gov.uk. Last revised 18/02/2019.
- Royal Pharmaceutical Society: Professional Guidance on the Administration of Medicines in Healthcare settings (2019)
- When PGDs are not required. SPS, 29.06.2022.
- FSRH Clinical Guideline: Intrauterine Contraception (March 2023) https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/
- NICE CG30. Long-acting reversible contraception. 02/07/2019

Appendix A. Staff Permitted to use Protocol Signature Sheet

Department name:_____

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 nurse or midwife below who has signed the protocol to work under it. *The authorising manager may wish to 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 health professional	Signature of 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 and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU (info.medicinesmanagement.powys@wales.nhs.uk) for audit purposes.
The nurse/ midwife 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, and to medicines management department (info.medicinesmanagement.powys@wales.nhs.uk), in conjunction with the Protocol Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.

Appendix B: POWYS TEACHING HEALTH BOARD SEXUAL HEALTH SERVICE IUD (Cu-IUD)/LNG-IUD CHECKLIST

Name: _____ **D.O.B.:** _____

Address: _____

GP contact details: _____

Risk Factors

UK MEC 4 /WHO 4: Absolute contraindications

Note the presence of **ONE (or more)** risk factors in this group contraindicates IUD usage

Condition	Present	Absent
Unexplained vaginal bleeding before evaluation if initiating IUD		
Gestational Trophoblastic Disease with persistently elevated hCG levels or malignant disease		
Post abortion sepsis, postpartum sepsis		
Pelvic Tuberculosis if initiating IUD		
Current PID, current symptomatic Chlamydia or purulent cervicitis or gonorrhoea (current) (if initiating IUD)		
Current Cervical cancer (awaiting treatment) if IUD is to be initiated		
LNG-IUD: Current breast cancer		
Endometrial cancer if IUD is to be initiated		

NB. Other absolute contraindications are current pregnancy or true allergy to the active ingredient or to any constituent (including Progesterone for LNG-IUD or copper for Cu-IUD, eg Wilson's disease).

UK MEC 3/ WHO 3: Conditions requiring careful consideration where risks generally outweigh advantages and where IUD should generally not be used.

Note: **These are all PGD/protocol exclusions.** Alternative contraceptive methods should be recommended and the potential risk of IUDs should be explained to women with **ANY** of these conditions. IUD should be the method of last choice for them, and careful monitoring required.

Condition	Present	Absent
48 hours to 4 weeks post partum		
Current asymptomatic Chlamydia (if initiating IUD)		
Developed Pelvic TB whilst on IUD		
Organ transplant with complications if IUD is to be initiated		
Long QT syndrome if IUD is to be initiated		
Uterine fibroids or other anatomical abnormalities causing distortion of uterine cavity		
Radical trachelectomy for cervical cancer		
Gestational Trophoblastic disease with decreasing hCG levels		
HIV with CD4 count less than 200 if initiating IUD		
LNG-IUD - Liver tumours (benign hepatocellular adenoma & malignant), severe decompensated liver cirrhosis		
LNG-IUD - Past history of breast cancer		
LNG-IUD - Developed IHD, stroke, TIA whilst on LNG-IUD		

NB CHECK DRUG INTERACTIONS FOR LNG-IUD

UK MEC 2/ WHO 2: Other conditions requiring caution but where advantages of IUD generally outweigh the theoretical or proven risks.

Note: For women with any of these problems, careful medical follow up is important.

Condition	Present	Absent
Under 20 years old		
Vaginitis, other current STI's (excluding HIV and hepatitis)		
Chlamydia, purulent cervicitis or Gonorrhoea developed while on IUD		
Lifestyle increased risk of STIs		
Unexplained vaginal bleeding or PID developed while on IUD		
Cervical cancer awaiting treatment if developed while on IUD		
Endometrial cancer developed while on IUD		
Anatomical abnormalities including cervical stenosis or cervical lacerations not distorting the uterine cavity or interfering with IUC insertion.		
Post Second trimester Termination		
HIV with CD4 count ≥ 200, or CD4 count < 200 whilst on IUD		
Complicated valvular & congenital heart disease (pulmonary hypertension, history of subacute bacterial endocarditis)		
Cardiomyopathy with impaired cardiac function		
Uncomplicated organ transplant or complicated transplant whilst on IUD		
Cu-IUD: Endometriosis		
CU-IUD: severe dysmenorrhoea		
Cu-IUD: Thalassaemia, sickle cell disease or iron deficiency anaemia		
LNG-IUD: SLE with or without antibodies, positive antiphospholipid antibodies		
LNG-IUD: Rheumatoid arthritis		
LNG-IUD: Symptomatic (including if treated by cholecystectomy, medically treated or current) or asymptomatic gallbladder disease		
LNG-IUD: History of cholestasis (past COC-related)		
LNG-IUD: Liver tumour: benign focal nodular hyperplasia		
LNG-IUD: Cervical intraepithelial neoplasia (CIN)		
LNG-IUD: Atrial fibrillation		
LNG-IUD: Hypertension with vascular disease		
If initiating LNG-IUD: Current and history of Ischaemic Heart Disease, History of stroke/TIA		
Condition	**Present**	**Absent**
LNG-IUD: Dyslipidaemias		

LNG-IUD: Multiple risk factors for cardiovascular disease (such as smoking, diabetes, hypertension, obesity and dyslipidaemias)		
LNG-IUD: Non-insulin dependent Diabetes, insulin dependent diabetes, individuals with Nephropathy/retinopathy/neuropathy or other vascular disease		
LNG-IUD: History of VTE, or current VTE		
LNG-IUD: Major surgery with prolonged immobilisation		
LNG-IUD: Known thrombotic mutation (eg. Factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies).		
LNG-IUD: Migraine with or without aura, or past history of migraine		
LNG-IUD: Breast conditions – undiagnosed mass/ breast symptoms, carriers of known gene Mutations associated with breast cancer (eg. BRCA1/BRCA2)		
Heavy or prolonged bleeding developed while on **IUD**, or Heavy or prolonged bleeding if considering initiating Cu-IUD		

Counselling (if at booking clinic)	**Discussed**
Mode of action	
Shown IUD	
Failure rate discussed	
Menorrhagia (IUD)	
Menstrual irregularity / hormonal effects (**LNG-IUD**)	
Chlamydia screen	
Interim contraception until insertion – **please state**	

COUNSELLING IUD CLINIC					
LMP		AGE		BP	
Current Day of Cycle		PARITY		PULSE	
Method used since					
Consent obtained (record who provided consent):					
If 13-16 years document capacity using Fraser guidelines:					
If under 13 or not competent to consent, record action taken:					
Shown IUD					
FAILURE RATE 1in 450		Ectopic risk			
Complications Failure to fit					

Risk of perforation						
Expulsion			Tampon use			
Infection			3/52 condoms			
Cu-**IUD**	Lifespan					
	Mennorhagia					
LNG-IUD	Lifespan					
	Menstrual Irregularity					
	Hormonal problems					
	Contraception after					
Chlamydia result						
Reason for coil.						
Contraception			Emergency coil			
Menorrhagia			Other			
INSERTION DETAILS						
UTERINE POSITION			VAGINA CLEANED Y / N			
ABNORMALITIES						
UTERUS SOUND/ SIZE						
Local Anaesthetic	None / Gel / block Route: Name/form/strength/dose: Batch: Expiry date: If administered via a protocol, record protocol title and version number:					
CERVICAL FIXATION	NONE	loose	closed	I toothed	2 toothed	other
Cervical canal checked						
DEGREE OF BLEEDING						
DEGREE OF PAIN	/ 10					
EASE OF INSERTION						
COIL USED Batch no & expiry date						
Coil fitted by						
POST COIL INSERTION PROBLEMS						
FURTHER ANALGESIA						
PROLONGED RECOVERY						

RESUSCITATION	

Thread teach by:	
Chaperone / person assisting:	
Practitioner's signature:	
Print name:	
Date and time:	
If administration is via PGD, record PGD title, version and number	

NOTES