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 insertion of the

Progestogen-Only Intra-Uterine Device (LNG-IUD)

for contraception

by Registered Nurses or Midwives

in Sexual Health Clinics

in Powys Teaching Health Board

Version number: **PGD 0160E**

Reference number: PGD 0160E
Valid from: 26/09/2024
Review date: 01/02/2026
Expiry date: 31/07/2026

Change History

Version number	Change details	Date
PGD 0160	Initial issue	01/04/2020
PGD 0160A	Review in line with SPS template version 1.3	08/02/2023
PGD 0160 B	Review in line with SPS template version 2.0: Amendments to exclusion, cautions, dose and frequency of administration and adverse effects sections to align with updated FSRH IUC guidance. Minor formatting/wording changes to align with other SPS PGD reproductive health templates.	01/08/2023
PGD 0160C	Updated according to SPS template version 2.1: Added "or until contraception no longer required if individual is over the age of 45 years of age at time of insertion" to frequency of insertion for Levonorgestrel 52mg intrauterine delivery system (Benilexa One Handed®). Minor formatting changes.	16/11/2023
PGD 0160D	Updated according to SPS template version 2.2: Updated duration of treatment for Mirena ® to 8 years, removed from off-label use, and added FSRH statement to reference section. Added note re low risk of breast cancer. Updated SLWG. Minor updates to PTHB PGD template.	15/05/2024
PGD 0160E	Updated according to SPS template version 2.3: Statement added to off-label use section regarding extended use of 8 years for all 52mg products in line with FSRH statement. Updated 'Dose and Frequency of Administration' section. Uterine perforation added as exclusion. Updated references. Updated SLWG members. Removal of Appendix B: Powys Teaching Health Board Sexual Health Service IUD (Cu-IUD)/LNG-IUD Checklist from this PGD. Minor updates to PTHB PGD template.	26/09/2024

This Powys Teaching Health Board (PTHB) PGD is based on template v2.3 developed on behalf of the Specialist Pharmacy Service, which had been peer

reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It had been approved by the Faculty for Sexual and Reproductive Health (FSRH) in February 2023.

Acknowledgements:

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PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	10/7/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	Signed by: Jacqui Seaton 71E8089DE3634C4...	9/30/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	10/9/2024
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	10/9/2024

Appendix A provides a staff 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 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation.

Characteristics of staff	
Qualifications and professional registration	Current contract of employment with Powys Teaching Health Board and providing Sexual Health Services. 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: • nurse or midwife currently registered with the Nursing and Midwifery Council (NMC) The practitioners must also fulfil the training and additional requirements detailed below. Check Appendix A: Staff accredited to use the Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with local policy (including the administration of levonorgestrel Intrauterine Device - LNG-IUD and knowledge of its uses, contraindications and adverse effects; be alert to changes in the BNF and Summary of Product Characteristics; the recognition, management and reporting of adverse drug reactions; and be competent to assess an individual's capacity to understand the nature and purpose of the treatment and capacity to give or refuse consent to treatment). Recommended requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH (sign in with your Athens account, then search for Contraception), HEIW or a university or as advised in the RCN training directory. Individuals working under this PGD should hold an in date FSRH Letter of Competence Intrauterine Techniques (LoC IUT) which

	has been achieved or recertified within the last 5 years. PGD users should have read thoroughly and be familiar with the FSRH IUC guidance. Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme, PTHB staff to access via ESR. Individuals working under this PGD will be required to administer local anaesthesia in line with local protocols. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or a minimum of level 2 safeguarding or the equivalent. The healthcare professional must ensure that they have an up to date certificate for Basic Life Support (BLS) and anaphylaxis, and be competent in the administration of adrenaline, as required by PTHB. Additionally, practitioners: • must have access to the Patient Group Direction and associated online resources **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A). The individual must complete a self-declaration of competence for LNG-IUD contraception insertion following training, 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.

	• Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions. • A minimum of Level 2 safeguarding passport • 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 must be competent, recognise their own limitations and personal accountability and act accordingly. • Evidence of training in BLS and anaphylaxis.
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Annual PGD training. • FSRH LoC IUT must be recertified every 5 years (refer to FSRH LoC IUT Training). • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, Life Support Skills, with evidence of appropriate Continued Professional Development (CPD). • Organisational PGD and/or medication training as required by employing Trust/organisation: updating at least every 2 years on levonorgestrel IUD (LNG-IUD). • Compliance with all mandatory NHS training including a minimum of safeguarding level 2. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

Clinical condition or situation to which this PGD applies	
Clinical condition or situation to which this PGD applies	Contraception **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.**
Criteria for inclusion	• Individual with childbearing potential (age from 13 to 55 years) presenting for contraception at sexual health clinics. • Informed consent given. Refer to PTHB Consent to Treatment and Examination Policy. In case of any doubt, contact medical team or gynaecologist. The individual should be informed they are being treated using a PGD. • Medical and drug history taken, no reason for exclusion. STI screening can be performed at the time of insertion as per FSRH guideline. For all clients aged 13 to 17 years, a CSERQ 4/15 questionnaire must be completed. For adults, if safe to do so, client responses to the targeted enquiry (Ask and Act) may highlight risk factors, which will indicate that the practitioner should complete the Safe Lives Risk Identification Checklist (DASH RIC). This will subsequently aid decision making regarding safeguarding and MARAC referrals. Any vulnerable adult or child protection safeguarding concerns or significant risk factors identified should be referred to the local PTHB Safeguarding team and Powys Children Services and PTHB safeguarding policies followed.
Criteria for exclusion	• Informed consent not given. 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 the individual is excluded" or "Action to be taken if the individual declines treatment". • Individuals under the age of 13 years. If a child is under 13 years of age and is known to have engaged in sexual activity this must be referred to Powys Children Service or CEOP Safety Centre, advice from the local

	Safeguarding lead should be sought and the local safeguarding policy should be followed. See Action to be taken if individual is excluded for further information. • Individuals 13 to 16 years of age and assessed as not competent using Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics. • Known or risk of pregnancy. • Any reported unprotected sexual intercourse (UPSI) within the last 3 weeks. • Less than 4 weeks postpartum (exclusion under this PGD does not necessarily mean that the medication is contra-indicated, but it would be outside its remit and another form of authorisation will be required). Note the LNG-IUD could be fitted post termination of pregnancy, ectopic pregnancy or miscarriage, in accordance with FSRH Guideline: Intrauterine contraception • Postpartum sepsis • Post-abortion sepsis • Gestational trophoblastic disease with decreasing or, persistently elevated β-hCG levels or malignancy Refer to the FSRH CEU clinical guideline Intrauterine Contraception (IUC) and clinical guidance 'switching' for specific guidance about starting and switching IUC: **Insertion of new device (no current IUC in situ)** ○ Any reported unprotected sexual intercourse (UPSI) since day 5 of a natural cycle, AND within the last 3 weeks. ○ If any UPSI >3 weeks ago where menstruation has not since occurred - negative pregnancy test required prior to insertion. **Changing to a new device (current IUC insitu and in date)** ○ Any reported unprotected sexual intercourse (UPSI) within the last 7 days **Changing to a new device (current IUC insitu but out of date)** ○ Any reported unprotected sexual intercourse (UPSI) within the last 3 weeks ○ If UPSI >3 weeks ago- negative pregnancy test required prior to insertion

	Cardiovascular Disease • Development of ischaemic heart disease, transient ischaemic attack or stroke whilst using the LNG-IUD. • For individuals with pre-existing arrhythmia, Eisenmenger physiology, single ventricle (or Fontan) circulation, long QT syndrome or impaired ventricular function, a vasovagal reaction could pose a serious risk of a significant cardiac event and therefore IUC procedures should be undertaken in a hospital setting. **Cancers** • Current or past history of breast cancer. • Malignant liver tumour (hepatocellular carcinoma). • Cervical cancer (awaiting treatment) • Endometrial cancer • Cervical cancer (resulting in radical trachelectomy). **Gastro-intestinal conditions** • Severe decompensated cirrhosis. • Benign liver tumour (hepatocellular adenoma). **Infections** • Current or recurrent pelvic inflammatory disease (PID) • Known chlamydial infection either symptomatic or asymptomatic • Known gonorrhoea infections either symptomatic or asymptomatic • Current purulent cervicitis or vaginitis • Known pelvic tuberculosis • HIV infection with CD4 <200cells/mm^3 **Anatomical abnormalities** • Distorted uterine cavity; congenital or acquired abnormality distorting the uterine cavity, including fibroids, incompatible with LNG-IUD insertion. **Other Conditions** • Unexplained vaginal bleeding suspicious of a serious medical condition, present before commencing the method • Organ transplant with complications • Acute porphyria • Previous endometrial ablation • Previous uterine perforation • Conditions outside of the clinical situations criteria

	• Any female who has a UKMEC score of 4 where LNG-IUD use is an unacceptable risk or UKMEC 3 where LNG-IUD risk of using the method outweighs the benefits (Refer to FSRH UKMEC) See Action to be taken if individual is excluded for further information.
Cautions including any relevant action to be taken	• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products (Refer to BNF/SPC for full list) • Individuals taking anticoagulants or antiplatelets - refer to FSRH CEU Statement Management of women taking anticoagulants or antiplatelet medications who request intrauterine contraception or subdermal implants. • Liaison with an individual's MDT or clinical specialist may be required with certain conditions (e.g. inherited bleeding disorders, cardiac disease, taking anticoagulants, Ehlers-Danlos syndromes (EDS), Postural tachycardia syndrome (PoTS). • Individuals at risk of an adrenal crisis will usually need to increase their steroid dose prior to, and for 24 hours after, IUC insertion and should ideally have their IUC procedure scheduled for early morning. • If an individual with PoTS has a history of postural syncope, advice should be sought from their cardiologist, as it may be recommended that insertion should be undertaken in a hospital setting. • Individuals with cardiac arrhythmias (other than long QT) discuss with relevant clinician. • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. 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).

Arrangements for referral for medical advice	Contact GP via the surgery or the emergency on-call service, document advice given. Where required, refer the individual to gynaecologist/ GUM consultant /level 3 Sexual Health services for advice, if applicable. Call medical cover for advice and document advice given.
Action to be taken if the individual is excluded	• Explain the reasons for exclusion to the individual and document reason and any action taken in the consultation record. • Where required refer the individual to a suitable health service provider (GP/ gynaecologist/ GUM consultant/ level 3 Sexual Health services) if appropriate and/or provide them with information about further options. • 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. 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

Action to be taken if the individual declines treatment	• Explain the consequences of refusing treatment • Record reason for decline, and any action taken in the consultation record. • Where required refer the individual to a suitable health service provider (GP/ gynaecologist/ GUM consultant/ level 3 sexual health services for advice) if appropriate and/or provide them with information about further options.

Description of Treatment	
Name, strength and formulation of drug	Levonorgestrel 13.5 mg intrauterine system (Jaydess®▼) Levonorgestrel 19.5mg intrauterine system (Kyleena®) Levonorgestrel 52mg intrauterine System (Levosert®) Levonorgestrel 52mg intrauterine system (Mirena®) Levonorgestrel 52mg intrauterine system (Benilexa One Handed®) **Note:** • This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to. • See http://www.mhra.gov.uk/spc-pil/ or http://www.medicines.org.uk for further information and further brand information including full details of adverse effects and interactions.
Legal category	POM
Black triangle	Jaydess®▼ Levonorgestrel 13.5 mg intrauterine system is a black triangle product. This information was accurate at the time of writing. See product SPCs at www.medicines.org.uk for indication of current black triangle status.
Route of administration	Intra-uterine Insert using aseptic or no-touch technique as per FSRH guidance on intrauterine contraception,

Off label use	Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD specifically includes inclusion criteria and dosage regimens which are outside the market authorisation for many of the available products but which are included within FSRH guidance: • When used for contraception only, any 52mg LNG-IUD may be retained until contraception no longer required in individuals over 45 years of age at time of insertion • Initial insertion after day 7 of the menstrual cycle if it is reasonably certain that the individual is not pregnant • Postpartum insertion between 4-6 weeks • Extended use of all 52mg LNG-IUDs to eight years for contraception (excluding Mirena ® and Levosert® which are within licence) 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 pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations 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 pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	• One LNG-IUD to be inserted (after removal of previous LNG-IUD if required). • Insert on day 1-5 of the menstrual cycle with no need for additional protection. • The LNG-IUD can be inserted at any time after day 5 of the menstrual cycle if it is reasonably certain

	that the individual is not pregnant. Additional contraception is then required for 7 days after insertion of the LNG-IUD. • For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines. **Frequency of LNG-IUD insertion:** • Levonorgestrel 13.5mg intrauterine delivery system (Jaydess®) - effective for up to 3 years • Levonorgestrel 19.5mg intrauterine delivery system (Kyleena®) - effective for up to 5 years. • Levonorgestrel 52mg intrauterine delivery system (Levosert ®) - effective for up to 8 years if individual is under the age of 45 years at time of insertion, or until the age of 55 if individual is over the age of 45 years at time of insertion. • Levonorgestrel 52mg intrauterine delivery system (Mirena®) - effective for up to 8 years, or until the age of 55 if individual is over the age of 45 years at time of insertion. This duration also applies to individuals who already have a device in-situ. • Levonorgestrel 52mg intrauterine delivery system (Benilexa One Handed®) - effective for up to 8 years if individual is under the age of 45 years of age at time of insertion or until the age of 55 if individual is over the age of 45 years at time of insertion.
Duration of treatment	For as long as individual requires contraception and has no contraindications to its use.
Quantity to be supplied	Single LNG-IUD is to be inserted per episode of care.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concomitant medications, including those purchased should be checked for interactions. A detailed list of drug interactions is available in the individual product SPC, which is available from the

	electronic Medicines Compendium website www.medicines.org.uk the BNF https://bnf.nice.org.uk and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/. Refer to a prescriber if any concern of a clinically significant drug interaction.
Identification and management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk. The LNG-IUD is generally well tolerated. The following possible adverse effects are commonly reported with LNG-IUD (but may not reflect all reported adverse effects): • Headache • Disturbance of bleeding patterns • Changes in mood • Weight change • Loss of libido • Breast tenderness • Acne Risk of ectopic pregnancy (see 'Written information and further advice to be given to individual') Insertion complications may include infection, expulsion, or perforation. Individuals should be advised on the signs that these may have occurred and the action to take if they become concerned. 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 the case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD 0017 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 levonorgestrel Intra-Uterine Device (indicating brand)**. • 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
Additional facilities and supplies	• Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline (epinephrine) 1:1000) and emergency drugs including atropine and oxygen according to local protocol.
Management of and reporting procedure for adverse reactions	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 or all suspected adverse reactions in children that may be attributable to the medication/ vaccine should be reported. If a black triangle medicine/ vaccine, report all suspected reactions. Guidance on the yellow card system is available at the back of the BNF, or using the above link. Record all adverse drug reactions (ADRs) in the individual's medical record and inform their GP. Report via organisation incident policy. All significant adverse drug reactions and any administration errors must be recorded. Report via Datix Once for Wales Reporting system. Note certain LNG-IUDs have additional Risk Minimisation materials (RMMs) to support safe use –

	organisations should ensure any RMMs supplied for the product/s used within their organisation are considered. See product profile at www.medicines.org.uk for further information.

Records to be kept	Record consultation details as required by local procedures. In addition, record:
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ If individual over 16 years of age and not competent, record action taken
	• Name of individual, address, date of birth
	• GP contact details where appropriate
	• Relevant past and present medical history, including medication and family history.
	• Any known allergies and previous adverse events
	• Details of insertion procedure to include:
	  ○ Printed name and signature of registered health professional
	  ○ Date of insertion
	  ○ Name/brand and strength of LNG-IUD inserted
	  ○ Batch number and expiry date of product in line with local procedure
	  ○ Bimanual examination and speculum findings. Record findings of vaginal examination and the position of the cervix/uterus as well as depth, use of instruments and other details of the insertion as per insertion protocol
	  ○ Uterine sounding
	  ○ Use of no touch technique
	  ○ Name of assistant/their role
	  ○ Analgesia or local anaesthetic used
	  ○ Problems encountered during insertion
	• Any reasons for exclusion or referral, including actions taken.
	• Advice given, including advice received from medical cover and advice given to individual, including advice given if excluded or declines treatment
	• Individual has been advised on the date/s for next appointment as required.

	• Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Any administration outside the terms of the product marketing authorisation and additional advice given relating to this and advice given (e.g. additional contraception for 7 days). • Recorded that administration is via Patient Group Direction (PGD), record PGD title, number and version Records should be signed and dated (or a password controlled e-records) 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.

Patient information	
Written information and further advice to be given to individual	• Provide patient information leaflet (PIL) provided with the original pack. • Explain mode of action, side effects, risks and benefits of the medicine • Advise about the risks of the medication including failure rates and serious side effects and the actions to be taken. • Advise about the possible symptoms of serious sequelae e.g. infection, ectopic pregnancy, expulsion and perforation and when to seek clinical advice. • Individuals should be advised that current use of progestogen-only contraceptives is associated with a small increased risk of breast cancer which reduces with time after stopping • Teach individual how to check threads and to seek clinical advice if threads not felt. • Advise when replacement of the LNG-IUD will be

	due. • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Ensure the individual has contact details of local service/sexual health services. • Give appropriate advice if medication is used off-label
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • Individual to seek further advice if they have any concerns

Key references (accessed November 2023, February 2024, May 2024)

- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- FSRH Clinical Guideline: Intrauterine Contraception (March 2023) https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/
- Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception May 2022 https://fsrh.org/Public/Documents/ceu-clinical-guidance-drug-interactions-with-hormonal.aspx
- Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use (Amended September 2019). UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) | FSRH
- Faculty of Sexual and Reproductive Healthcare (2016 Clinical Guideline: Quick Starting Contraception (April 2017) FSRH Clinical Guideline: Quick Starting Contraception (April 2017) | FSRH
- Faculty of Sexual and Reproductive Healthcare (2019) Service standards for record keeping https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-record-keeping-july-2019/
- FSRH CEU Resource: New one-handed, reloadable 52mg levonorgestrel-releasing intrauterine system FSRH CEU resource: New one-handed, reloadable 52mg levonorgestrel-releasing intrauterine system | FSRH (2021)
- FSRH CEU Statement: Management of women taking anticoagulants or antiplatelet medications who request intrauterine contraception or subdermal implants (March 2017)
- FSRH CEU Statement: Mirena® 52mg LNG-IUD extension of licence for contraception to 8 years (2024) FSRH CEU Statement: Mirena 8 years contraception (Jan 2024) | FSRH
- Faculty of Sexual and Reproductive Healthcare (2023) Response to new study on use of combined and progestogen-only hormonal contraception and breast cancer risk. FSRH Response to new study on use of CHC and POC and breast cancer risk (March 2023) - Faculty of Sexual and Reproductive Healthcare
- FSRH CEU Statement: Extended use of all 52mg LNG-IUDs for up to eight years for contraception (May 2024). FSRH CEU Statement: Extended use of all 52mg LNG-IUDs for up to eight years for contraception (May 2024) - Faculty of Sexual and Reproductive Healthcare

Appendix A Staff accredited to use the 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 required for audit purposes. This list should be kept by PTHB for 25 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) Specify in comments"	Comments
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.