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.

PATIENT GROUP DIRECTION (PGD)

Insertion of the Progestogen-Only Intra-Uterine Device (LNG- IUD) in BPAS Clinics

Version Number 2.3

Change History	
Version and Date	**Change details**
Version 1.0 August 2020	New template
Version 1.1 November 2020	Additional of Jaydess®▼ Levonorgestrel 13.5 mg intrauterine system as a black triangle product. Acute porphyria added as exclusion. *Note: Clients with [acute] porphyria already excluded from treatment at BPAS.*
Version 1.2 March 2021	Levosert® license revised to usage period from 5 to 6 years for when indication is for contraception. Dose and frequency of administration section amended to read: ○ Levonorgestrel 52mg Intrauterine System (Levosert ®) - effective for up to 6 years or until contraception no longer required if individual is over the age of 45 years of age at time of insertion. *Version 1.2 authorised for use in BPAS 22/12/2022.*
Version 1.3 September 2022	Benilexa One Handed® 52mg levonorgestrel-releasing intrauterine system added to Name, strength & formulation of drug and Dose and frequency of administration sections. eLFH PGD e learning added to training section *Version 1.3 not adopted by BPAS as Benilexa One Handed® 52mg levonorgestrel-releasing intrauterine system not in use in BPAS. eLFH is recommended training.*
Version 1.2 May 2022	Expiry date extended to full 3 year term from authorisation of PGD in November 2020. *Archived 2023*
Version 2.0 April 2023 *Not implemented*	Updated template. 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.
Version 2.1 September 2023 *Not implemented*	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®).
Version 2.2 August 2024	PGD reinstated and reviewed with 2023 updates. Updated duration of treatment for Mirena ® to 8 years, removed from off-label use, and added FSRH statement to reference section. Statement added to off-label use section regarding

	extended use of 8 years for all 52mg products in line with FSRH statement. Added note re low risk of breast cancer. Updated 'Dose and Frequency of Administration' section. Uterine perforation added as exclusion. Updated references. Updated SLWG members.

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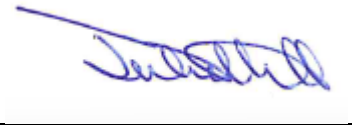
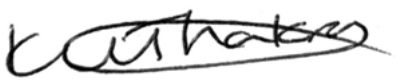
PGD DEVELOPMENT GROUP

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

Name	Designation
Dr Cindy Farmer	Vice President, Professional Learning and Development FSRH
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee FSRH
Elaine Scott	Senior Quality Matron British Pregnancy Advisory Service (BPAS)
Kalpesh Thakrar	Lead Pharmacist British Pregnancy Advisory Service (BPAS)
Tanya Lane	Designate Clinical Excellence Lead for Contraception and Sexual Health, Registered Nurse, MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Heather Randle	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Alison Crompton	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Portia Jackson	Lead Pharmacist iCaSH, Cambridgeshire Community Services NHS Trust
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service
Rosie Furner (Working Group Co-ordinator)	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service

BPAS PGD Organisational Authorisations:

This PGD is not legally valid until it has had the relevant organisational authorisations below.

Name	Job title and organisation	Signature	Date
Mary Sexton	BPAS Clinical Director		19/08/2024
Dr Julie Miller	BPAS Deputy Medical Director		16/08/2024
Kalpesh Thakrar	BPAS Lead Pharmacist		30/07/2024

Authorising Body:

Cheshire and Merseyside ICB	*Rowan Pritchard -Jones*		*07/11/2024*

Responsible person who has approved this PGD on behalf of BPAS

Name: Heidi Stewart

Position: BPAS Chief Executive

Signature:

Date:  22/08/2024

Glossary	
BPAS	British Pregnancy Advisory Service
BASHH	British Association for Sexual Health and HIV
BLS	Basic life support
BNF	British National Formulary
FSRH	Faculty of sexual and reproductive healthcare
GUM	Genitourinary medicine
IUC	Intrauterine contraception
LNG-IUD	Progesterone only intrauterine device
MHRA	Medicines Health Regulatory Agency
NICE	National Institute for Health and Care Excellence
NMC	Nursing and Midwifery Council
SmPC	Summary of medicinal product characteristics
STI	Sexually transmitted infection
UPSI	Unprotected sexual intercourse

1. Characteristics of Staff

Qualifications and professional registration	• NMC Registered Nurse • NMC Registered Midwife With a current contract of employment with BPAS Practitioners must also fulfil the additional requirements listed below.
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 patients ensuring safe provision of the medicines listed in accordance with local policy. Recommended requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE 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 Individuals working under this PGD will be required to administer local anaesthesia in line with local protocols/PGDs. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent. Additionally, practitioners: • Must have completed appropriate training for working under a PGD for the supply / administration of medicines (see training requirements in the BPAS PGD policy) • Must be familiar with the medicine and observant to changes in the BNF and Summary of Product Characteristics (SmPC) • Must be competent in the recognition and management of adverse reactions, including anaphylaxis • Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum • Must have access to the PGD and associated online resources **The practitioner must be authorised by name, under the current version and terms of this PGD in the Approved Practitioner List before working to it.**
Competency	• Individuals operating under this PGD must be assessed as competent

assessment	(see Appendix A) or complete a self-declaration of competence for LNG-IUD contraception insertion. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
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. • FSRH LoC IUT must be recertified every 5 years. Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Contraception
Criteria for inclusion	• Individual (age from menarche to 55 years) presenting for contraception. • Informed consent given.
Criteria for exclusion	• Informed consent not given. • Individuals under 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. • If any UPSI >3 weeks ago where menstruation has not occurred - negative pregnancy test required prior to insertion. • Postpartum sepsis • Post-abortion sepsis • Gestational trophoblastic disease with decreasing or, persistently elevated β-hCG levels or malignancy **Cardiovascular Disease** • Development of ischaemic heart disease, transient ischaemic attack or stroke whilst using the LNG-IUDS. • 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 IUD insertion. **Other Conditions** • Unexplained vaginal bleeding suspicious of a serious medical condition, present before commencing the method • Organ transplant with complications • Acute porphyria *(clients with this condition are already excluded from treatment at BPAS)* • Previous endometrial ablation • Previous uterine perforation **Interacting medicines** – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk
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. • If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. • 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.

Action to be taken if the individual is excluded or declines treatment	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & 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®) **Note:** • This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to and the above list edited to reflect local formularies. • 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 or immediate PPIUC technique.
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 maybe 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 • Extended use of all 52mg LNG-IUDs to eight years for contraception (excluding Mirena ® which is 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 IUS (Jaydess®) - effective for up to 3 years ○ Levonorgestrel 19.5mg intrauterine system (Kyleena®) - effective for up to 5 years. ○ Levonorgestrel 52mg Intrauterine System (Levosert ®) - effective for up to 6 years or until contraception no longer required if individual is over the age of 45 years of age at time of insertion. ○ Levonorgestrel 52mg IUS (Mirena®) - effective for up to 8 years or until contraception no longer required if individual is over the age of 45 years of age 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.
Drug interactions	All concomitant medications 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 www.bnf.org 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 & 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 www.bnf.org 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 • 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.
Additional facilities and supplies	• Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000) and emergency drugs including atropine and oxygen according to local protocol.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/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 • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy. • 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
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.
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 she has any concerns

Records	**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
	• Details of insertion procedure to include:
	  ○ Name of registered health professional
	  ○ Date of insertion
	  ○ Name/brand of LNG-IUD inserted
	  ○ Batch number and expiry date of administered
	  ○ Bimanual examination and speculum findings
	  ○ Uterine sounding
	  ○ Use of no touch technique
	  ○ Name of assistant/their role
	  ○ Analgesia or local anaesthetic used
	  ○ Problems encountered during insertion
	• Advice given, 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)
	
	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.

4. Key references

Key references ~~(accessed March 2020/September 2022)~~ (accessed November 2023, February 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/documents/ceuguidanceintrauterinecontraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use. https://www.fsrh.org/documents/ukmec-2016/ • Faculty of Sexual and Reproductive Healthcare (2016 Clinical Guideline: Quick Starting Contraception (April 2017) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/ • 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 Statement: Mirena® 52mg LNG-IUD extension of licence for contraception to 8 years (2024) https://www.fsrh.org/news/fsrh-ceu-statement-mirena-52mg-lng-iud-extension-of-licence/ • 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: Approved Practitioner List

Patient Group Direction (PGD) name:	Insertion of the Progestogen-Only Intra-Uterine Device (LNG-IUD) v2.2	
	Valid from: 01/08/2024	**Expiry:** 30/07/2026

Registered health professional

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

PGDs do not remove 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. The practitioner MUST sign this document before they can work under this PGD.

I confirm that I have read and understood the contents of this PGD. I confirm that I am willing and competent to work to this PGD within my professional code of conduct.				
Name (print)	**Designation**	**NMC PIN**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation for the above named health care professionals who have signed the PGD to work under it.				
Name	**Position**	**BPAS Treatment Unit**	**Signature**	**Date:**

Note to authorising manager

- Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
- If registered health professional signatures need to be added at a later date, e.g. due to staffing changes, a separate Approved Practitioner List must be signed, ensuring the correct PGD name and version is detailed.
- This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

- This list must be stored by the Treatment Unit in a designated folder and be available for immediate inspection, alongside any training / competency records. If a registered professional works across multiple sites, they must sign the Approved Practitioner List for each PGD at each BPAS site where they will use the PGD.