

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 Rotherham, Doncaster, and South Humber (RDaSH) NHS Foundation Trust.

Version Number 2.1

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.
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:
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 2.0 April 2023	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	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®).

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	August 2023
Review date	February 2026
Expiry date:	July 2026

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.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Dr Cindy Farmer	Vice President, General Training FSRH
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee FSRH
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Sim Sesane	CASH Nurse Consultant 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)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Consultant
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
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 (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Graeme Tosh	Medical Director	4	24/10/23
Stephen Davies	Chief Pharmacist	Danes	30/00/23
Sheila Lloyd	Director of Nursing and AHPs	Stlatd	2010/23
Anil Rajpal	Senior Pharmacist	Buf Rap	7/11/23
Tina Proctor	Nurse Consultant Senior representative of professional group using the PGD	That	7/11/23

Committee Approval:

NAME	DATE
Medicines Management Committee	20.10.2023

Date of Implementation 08.11	.2023
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1. Characteristics of Staff

Qualifications and	Current contract of employment within a Local Authority or NHS
professional registration	commissioned service or an NHS Trust/organisation.
	Registered healthcare professional listed in the legislation as able to
In Mile I done in the co	practice under Patient Group Directions.
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.
	m accordance man recal pency.
	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.
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	Individual has undertaken appropriate training for working under PGDs
	for the supply and administration of medicines. Recommended training
	- <u>eLfH PGD elearning programme</u>
	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.
	3
	The healthcare professional must ensure that they have an up to date
	certificate for Basic Life Support (BLS) and anaphylaxis as required by
	the employing Trust/organisation
Competency	Individuals operating under this PGD must be assessed as
assessment	competent (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	Individuals operating under this PGD are personally responsible
competency	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 a	any medication rests with the individual registered health professional

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	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. Risk of pregnancy Any reported unprotected sexual intercourse (UPSI) within the last 3 weeks. Over 48 hours and less than 4 weeks postpartum (note the LNG-IUD can be fitted immediately post-partum, post termination of pregnancy, ectopic pregnancy or miscarriage) 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 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/mm³

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

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 <u>Management of women taking</u> <u>anticoagulants or antiplatelet medications who request</u> <u>intrauterine contraception or subdermal implants</u>
- 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®) 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 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
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
- Mirena® effective for up to 6 years
- 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

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 <u>changing from one contraceptive method</u> to <u>another</u>, and when to start after an <u>abortion and</u> <u>postpartum</u>, 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 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 intrauterine delivery system (Mirena®) - 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.

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	Leven availated 50mm introvitaring delivery avators
	 Levonorgestrel 52mg intrauterine delivery system (Benilexa One Handed®) - 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.
Duration of treatment	For as long as individual requires contraception and has no
Duration of treatment	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
3	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 <u>www.medicines.org.uk</u> the BNF
	www.bnf.org and FSRH CEU Guidance: Drug Interactions with
	Hormonal Contraception https://www.fsrh.org/standards-and-
	<u>guidance/documents/ceu-clinical-guidance-drug-interactions-</u> with-hormonal/
	<u>with-normonal/</u>
	Refer to a prescriber if any concern of a clinically significant
	drug interaction.
Identification & management	A detailed list of adverse reactions is available in the SPC,
of adverse reactions	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
	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	Access to working telephone
supplies	Suitable waste disposal facilities
- applied	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	Healthcare professionals and patients/carers are
procedure for adverse	encouraged to report suspected adverse reactions to the
reactions	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 madical record.
	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 <u>www.medicines.org.uk</u> for further information
Written information and	Provide patient information leaflet (PIL) provided with the
further advice to be given to	original pack.
individual	Explain mode of action, side effects, risks and benefits of
	the medicine
	Advise about the risks of the medication including failure Advise and earlies and the actions to be taken.
	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
	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.
D	Individual to seek further advice if they have any concerns
Records	Record:
	The consent of the individual and If individual is under 13 years of age record action.
	 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 and family history.
	medication and family history.
	Any known allergiesDetails 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 product in line with
	local procedure
	Bimanual examination and speculum findings
	Uterine sounding
	Use of no touch technique
	Name of assistant/their role Analgosia or local anaesthetic used
	Analgesia or local anaesthetic usedProblems encountered during insertion
	 Problems encountered during insertion Advice given, including advice given if excluded or declines
	treatment
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- 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 January 2023)

- 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/ceuguidanceintrauterinecont-raception/
- 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 Resource: New one-handed, reloadable 52mg levonorgestrel-releasing intrauterine system https://www.fsrh.org/news/fsrh-ceu-resource-new-one-handed-reloadable-52mg-levonorgestrel/ (2021)

Appendix A – Example registered health professional authorisation sheet PGD Name/Version Valid from: Expiry:

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

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

Patient group directions 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.				
Name	Designation	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 on behalf of RDaSH NHS Foundation Trust for the above				
named health care professionals who have signed the PGD to work under it.				
Name	Designation	Signature	Date	

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

This information will be retained by the Chief Pharmacist of RDASH NHS Foundation Trust.