University Hospitals Sussex
NHS Foundation Trust

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 System (IUS) in University Hospitals Sussex NHS Foundation Trust Sexual Health & Contraception (SHAC) Service

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1.0 August 2020	New template

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

Approved date: April 2021 Expiry date: 31st July 2023

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1st August 2020
Review date	Feb 2023
Expiry date:	31st July 2023

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 July 2020.

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

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michael Nevill	Director of Nursing British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant Marie Stopes UK
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Pan London PGD working group
Dr Sarah Pillai	Pan London PGD working group
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

PGD approval - meets local need and guidelines

Name	Job title and organisation	Signature	Date
Lead author: Reproductive Health PGDs Short Life Working Group	As listed on Page 2/3		
Lead Doctor: Dr Juliet Bowie	Associate Specialist, SHAC Service, UHSussex	Email approval	03/12/20
Lead pharmacist: Claire Richardson	Lead Pharmacist, HIV & Sexual Health Service, UHSussex	Email approval	10/12/20
Lead Clinician for area: Dr Debbie Williams	Consultant (HIV & GUM), SHAC, UHSussex	Email approval	26/11/20
Reviewed by: Dr Daniel Richardson Ruth Bailey	Consultant HIV & SHAC Service, UHSussex Nurse Team Leader, SHAC Service, UHSussex	Email approval Email approval	25/11/20 03/12/20
Representative of other professional group using PGD Wendy Gardiner	Advanced Nurse Practitioner, SHAC Service, UHSussex	Email approval	25/11/20

Organisational authorisations

University Hospitals Sussex NHS Foundation Trust authorises this PGD for use by the services or providers listed below:
Sexual Health & Contraception (SHAC) Service.
Limitations to authorisation
Only Registered Nurses who work within the SHAC Service, hold a relevant contraception qualification, and are signed to the PGD.

Name	Signature & Name	Date
Chair of PGD Group	Joanne Pendlebury – email approval	April 2021
Chief Pharmacist	Mike Cross – email approval	April 2021
Medicines Governance Group chair	Mike Okorie – email approval	April 2021

Local enquiries regarding the use of this PGD may be directed to uhsussex.pgdgroup@nhs.net or PGD group chair.
Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

Approved date: April 2021 Expiry date: 31st July 2023

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to 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. 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. Individuals working under this PGD may 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. Register and complete PGD training module (certificate can be printed out as evidence) https://portal.e-lfh.org.uk/ (3 yearly) Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions. Has undertaken appropriate Trust approved resuscitation training.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for IUS 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, including: ➢ PGD e-learning 3 yearly ➢ Up to date with mandatory training
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. • Consent given.
Criteria for exclusion	• 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. • Any reported unprotected sexual intercourse (UPSI) within the last 3 weeks. • If any UPSI >3 weeks ago where menstruation has not occurred - negative pregnancy test required prior to insertion. • Over 48 hours and less than 4 weeks postpartum (note the IUS can be fitted immediately 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 **Cardiovascular Disease** • Development of ischaemic heart disease, transient ischaemic attack or stroke whilst using the IUS. • Known long QT syndrome **Cancers** • Current or past history of breast cancer. • Benign liver tumour (hepatocellular adenoma). • Malignant liver tumour (hepatocellular carcinoma). • Cervical cancer (awaiting treatment) • Endometrial cancer • Radical trachelectomy **Gastro-intestinal conditions** • Severe decompensated cirrhosis. **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 IUS insertion. **Other Conditions** • Unexplained vaginal bleeding suspicious of a serious medical condition, present before commencing the method • Organ transplant with complications **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 specific FSRH guidance. • 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 (**N.B**. SHAC

	Service: Levosert not routinely available at 2020 but included in this PGD as it may be added to formulary in near future). • 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
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 may be retained until contraception no longer required in individuals over 45 years of age at time of insertion for Mirena® only. • Initial insertion after day 7 of the menstrual cycle. • 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 IUS to be inserted (after removal of previous IUS if required). • Insert on day 1-7 of the menstrual cycle with no need for additional protection • The IUS can be inserted at any time after day 7 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 IUS. • 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 IUS 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 5 years. ○ Levonorgestrel 52mg IUS (Mirena®) - effective for up to 5 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 IUS is to be inserted per episode of care.
Storage	Medicines must be stored securely according to national guidelines.
Drug 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/
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 IUS is generally well tolerated. The following possible adverse effects are commonly reported with IUS (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	• Healthcare professionals and patients/carers are 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 medical record. • Report via organisation incident policy.
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 • Teach individual how to check threads and to seek clinical advice if threads not felt • Advise when replacement of the IUS 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 o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. o 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: o Name of registered health professional o Date of insertion o Name/brand of IUS inserted o Batch number and expiry date of administered o Bimanual examination and speculum findings o Uterine sounding o Use of no touch technique o Name of assistant/their role o Analgesia or local anaesthetic used o 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.

Audit

Plan for audit, It is essential for PGD renewal that audits have occurred**.**	Service audit to be completed using the recommended UHSussex PGD audit template. N. B. Individual PGD users should keep records to audit their own use of PGDs / procedures.
Frequency	Minimum of once in lifetime of PGD 2 years after start date of PGD to inform PGD review.
Nominated lead to manage audit	Advanced Nurse Practitioner/Clinical Nurse Specialist, SHAC Service will manage Service PGD audit process and support / guide those completing the audit. SHAC Nurse(s) who use the PGD will complete the service audit.

4. Key references

Key references (accessed March 2020)	• 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 • Faculty of Sexual and Reproductive Health Clinical Guideline: (December 2014, updated April 2019) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-injectables-dec-2014/

	• FSRH Clinical Guideline: Intrauterine Contraception (April 2015, amended September 2019) https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/ • Faculty of Sexual and Reproductive Health CEU Guidance: Drug Interactions with Hormonal Contraception (January 2017, last reviewed 2019) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ • 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/ • Learning for Health https://portal.e-lfh.org.uk/ • UHSussex policies and procedures: ➢ C085 – Policy for Patient Group Directions: accessed on UH Sussex intranet https://nww.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions ➢ SHAC Service Standard Operating Procedure for supply of medicines following telephone / video consultations.

Appendix A - Registered health professional authorisation sheet

PGD Name/Version: *Insertion of the Progestogen-Only Intra-Uterine System (IUS) (Version 1.0)*

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 University Hospitals Sussex 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.

SHAC SERVICE RETENTION OF PGD AUTHORISATION RECORDS

Records of the authorisation of nurses for the use of this PGD are stored as follows:

- **HARD COPY:** A paper copy of the signature sheet will be kept with the PGD in the PGD Master Copy File in the SHAC Nurse Management Office (if hard copy retained).

- **ELECTRONIC RECORD:**

  - A scanned copy of each authorisation sheet is saved on to the service specific file.

  - An electronic record of SHAC Nurse authorisation for this PGD is recorded on the SHAC Service PGD Assessment Record database which is stored on to the service specific file.

- **INDIVIDUALS:**

  - Individual nurses are provided with the PGD assessment sheet which details the assessment process for PGD approval for their own records.

  - A copy of this document is stored in the individual nurses' Personal File.