





**Patient Group Direction For Insertion Of The Progestogen-Only Intra-Uterine Device (LNG-IUD) In NHS Grampian, Orkney And Shetland**

<b>Lead Author:</b> Adapted from FSRH/SPS PGD Insertion of the Progestogen-Only Intra- Uterine Device (LNG-IUD) Version 2.3 – Date published July 2024		<b>Approver:</b> NoS PGD Group  <b>Authorisation:</b> NHS Grampian
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<b>Signature:</b> 		<b>Signature:</b> 
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<b>NoS Identifier:</b> NoS/PGD/LNG_IUD/1408	<b>Review Date:</b> February 2026  <b>Expiry Date:</b> July 2026	<b>Date Approved by NoS:</b> 23 <sup>rd</sup> September 2023 (Amended July 2024)
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NHS Grampian, Orkney, Shetland, have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

**Uncontrolled when printed**

**Version 2.3 (Amended July 2024)**

**Revision History for NoS:**

<b>Nos PGD that has been superseded</b>	PGD supersedes NHSG/PGD/IUS/Levonorgestrel/MGPG1408, Version 2 (Version 2.1 and 2.2 unpublished)	
<b>Date of change</b>	<b>Summary of Changes</b>	<b>Section heading</b>
August 2024	Reference to NoS Appendix 1 and 2.	Authorisation
August 2024	Removed SPS advised training and added TURAS NoS PGD training link added.	Initial Training
August 2024	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
August 2024	Additional facilities and supplies added as per NoS Sexual health Template added.	Additional facilities and supplies
August 2024	Information added about recording on HEPMA added.	Records
August 2024	Statement removed about local authority.	Qualifications and professional registration

**FSRH/SPS Revision**

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 1.0 August 2020	New template
Version 1.1 November 2020	Additional of Jaydess®▼ Levonorgestrel 13.5mg 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: <ul style="list-style-type: none"> <li>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.</li> </ul>
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 and Date	Change details
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®).
Version 2.2 April 2024	Additional indication of postpartum intrauterine contraception (PPIUC). 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.
Version 2.3 July 2024	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.

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.



## Authorisation


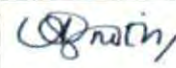
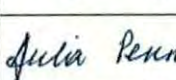
This specimen Patient Group Direction (PGD) template has been produced by FSRH/SPS and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer LNG-IUD under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines administered in accordance with this PGD.


NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the LNG-IUD has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD ([Appendix 1](#)).

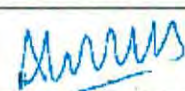
A Certificate of Authorisation ([Appendix 2](#)) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Linda Sandilands	Signature		Date Signed	16/08/2024
Pharmacist	Alison Smith	Signature		Date Signed	31/08/2024
Nurse	Julia Penn	Signature		Date Signed	16/08/2024

### Approved for use within NoS by:

NoS Group Chair	Signature	Date Signed
Lesley Coyle		02/10/2024

### Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Deputy Chief Executive		05/10/2024

**Version 2.3 – Approved for Grampian, Orkney and Shetland from 5<sup>th</sup> October 2024**

## 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.

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

## 1. Characteristics of Staff

<b>Qualifications and professional registration</b>	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
<b>Initial training</b>	<p>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.</p> <p>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.</p> <p>Immediate postpartum intrauterine contraception (PPIUC) insertion training is not part of the FSRH LoC IUT. The insertion procedure for immediate PPIUC is different to that of standard IUC insertion and should only be performed by those who have been trained in this technique. Theoretical training information for PPIUC can be found in the FSRH Member's Training hub and clinicians should follow/develop local pathways for practical training.</p> <p>PGD users should have read thoroughly and be familiar with the <a href="#">FSRH IUC guidance</a>.</p> <p>Have undertaken NoS PGD module training on <a href="#">TURAS</a> Learn.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.</p> <p>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</p>
<b>Competency assessment</b>	<ul style="list-style-type: none"> <li>Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for LNG-IUD contraception insertion.</li> <li>Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></li> </ul>

<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>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.</li> <li>FSRH LoC IUT must be recertified every 5 years.</li> <li>Organisational PGD and/or medication training as required by employing Trust/organisation.</li> </ul>
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

<b>Clinical condition or situation to which this PGD applies</b>	Contraception
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>Individual (age from menarche to 55 years) presenting for contraception.</li> <li>Informed consent given.</li> <li>An individual under 16 years of age may give consent for the administration of LNG-IUD, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the administration, administer should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>Informed consent not given.</li> <li>Individuals under 16 years of age and assessed as not competent using Fraser Guidelines.</li> <li>Individuals 16 years of age and over and assessed as lacking capacity to consent.</li> <li>Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics.</li> <li>Risk of pregnancy</li> <li>Any reported unprotected sexual intercourse (UPSI) within the last 3 weeks.</li> </ul>



- Over 48 hours and less than 4 weeks postpartum (note the LNG-IUD can be fitted immediately postpartum, post termination of pregnancy, ectopic pregnancy or miscarriage)
- Postpartum sepsis
- Post-abortion sepsis
- Gestational trophoblastic disease with decreasing or, persistently elevated  $\beta$ -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.



	<p><b>Cancers</b></p> <ul style="list-style-type: none"> <li>• Current or past history of breast cancer</li> <li>• Malignant liver tumour (hepatocellular carcinoma)</li> <li>• Cervical cancer (awaiting treatment)</li> <li>• Endometrial cancer</li> <li>• Cervical cancer (resulting in radical trachelectomy).</li> </ul> <p><b>Gastro-intestinal conditions</b></p> <ul style="list-style-type: none"> <li>• Severe decompensated cirrhosis</li> <li>• Benign liver tumour (hepatocellular adenoma).</li> </ul> <p><b>Infections</b></p> <ul style="list-style-type: none"> <li>• Current or recurrent pelvic inflammatory disease (PID)</li> <li>• Known chlamydial infection either symptomatic or asymptomatic</li> <li>• Known gonorrhoea infections either symptomatic or asymptomatic</li> <li>• Current purulent cervicitis or vaginitis</li> <li>• Known pelvic tuberculosis</li> <li>• HIV infection with CD4 &lt;200cells/mm<sup>3</sup>.</li> </ul> <p><b>Anatomical abnormalities</b></p> <ul style="list-style-type: none"> <li>• Distorted uterine cavity; congenital or acquired abnormality distorting the uterine cavity, including fibroids, incompatible with LNG-IUD insertion.</li> </ul> <p><b>Other Conditions</b></p> <ul style="list-style-type: none"> <li>• Unexplained vaginal bleeding suspicious of a serious medical condition, present before commencing the method</li> <li>• Organ transplant with complications</li> <li>• Acute porphyria</li> <li>• Previous endometrial ablation</li> <li>• Previous uterine perforation.</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p>	<ul style="list-style-type: none"> <li>• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.</li> <li>• 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.</li> <li>• Individuals taking anticoagulants or antiplatelets - refer to FSRH CEU Statement <a href="#">Management of women taking anticoagulants or antiplatelet medications who request intrauterine contraception or subdermal implants</a></li> </ul>

	<ul style="list-style-type: none"> <li>• 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).</li> <li>• 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.</li> <li>• 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.</li> <li>• Individuals with cardiac arrhythmias (other than long QT) discuss with relevant clinician.</li> <li>• Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.</li> </ul>
<b>Action to be taken if the individual is excluded or declines treatment</b>	<ul style="list-style-type: none"> <li>• Explain the reasons for exclusion to the individual and document in the consultation record.</li> <li>• Record reason for decline in the consultation record.</li> <li>• Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.</li> </ul>

### 3. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<p>Levonorgestrel 13.5mg 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®)</p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• See <a href="http://www.mhra.gov.uk/spc-pil/">http://www.mhra.gov.uk/spc-pil/</a> or <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a> for further information and further brand information including full details of adverse effects and interactions.</li> </ul>
<b>Legal category</b>	POM

<b>Black triangle</b>	<p>Jaydess®▼ Levonorgestrel 13.5mg intrauterine system is a black triangle product.</p> <p>This information was accurate at the time of writing. See product SPCs at <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a> for indication of current black triangle status.</p>
<b>Route of administration</b>	<p>Intra-uterine</p> <p>Insert using aseptic or no-touch technique as per <a href="#">FSRH guidance on intrauterine contraception</a>, or immediate PPIUC technique.</p>
<b>Off label use</b>	<p>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).</p> <p>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:</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Initial insertion after day 7 of the menstrual cycle if it is reasonably certain that the individual is not pregnant</li> <li>• Postpartum insertion within 48 hours of birth or between 4-6 weeks</li> <li>• Extended use of all 52mg LNG-IUDs to eight years for contraception (excluding Mirena® which is within licence)</li> </ul> <p>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.</p> <p>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.</p>

<b>Dose and frequency of administration</b>	<ul style="list-style-type: none"> <li>• One LNG-IUD to be inserted (after removal of previous LNG-IUD if required).</li> <li>• Insert on day 1-5 of the menstrual cycle with no need for additional protection.</li> <li>• 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.</li> <li>• For guidance on <a href="#">changing from one contraceptive method to another</a>, and when to start after an <a href="#">abortion and postpartum</a>, refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines.</li> <li>• Insert within 48 hours of birth (Immediate postpartum intrauterine contraception (PPIUC)). The insertion procedure for immediate PPIUC is different to that of standard IUC insertion and should only be performed by those who have been trained in this technique.</li> </ul> <p><b>Frequency of LNG-IUD insertion:</b></p> <ul style="list-style-type: none"> <li>• Levonorgestrel 13.5mg intrauterine delivery system (Jaydess®) - effective for up to 3 years.</li> <li>• Levonorgestrel 19.5mg intrauterine delivery system (Kyleena®) - effective for up to 5 years.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul>
<b>Duration of treatment</b>	For as long as individual requires contraception and has no contraindications to its use.
<b>Quantity to be supplied</b>	Single LNG-IUD is to be inserted per episode of care.
<b>Storage</b>	Medicines must be stored securely according to national guidelines.



<b>Drug interactions</b>	<p>All concomitant medications should be checked for interactions.</p> <p>A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> the BNF <a href="http://www.bnf.org">www.bnf.org</a> and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception <a href="https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/">https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/</a></p> <p>Refer to a prescriber if any concern of a clinically significant drug interaction.</p>
<b>Identification &amp; management of adverse reactions</b>	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="http://www.bnf.org">www.bnf.org</a></p> <p>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):</p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Disturbance of bleeding patterns</li> <li>• Changes in mood</li> <li>• Weight change</li> <li>• Loss of libido</li> <li>• Breast tenderness</li> <li>• Acne</li> </ul> <p>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.</p>
<b>Additional facilities and supplies</b>	<ul style="list-style-type: none"> <li>• Access to working telephone</li> <li>• Suitable waste disposal facilities</li> <li>• Suitable storage facilities</li> <li>• An acceptable level of privacy to respect individual's right to confidentiality and safety</li> <li>• Access to medical support (this may be via the telephone Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel.</li> <li>• A copy of this current PGD in print or electronically.)</li> <li>• Suitable waste disposal facilities</li> </ul>

	<ul style="list-style-type: none"> <li>• Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000) and emergency drugs including atropine and oxygen according to local protocol.</li> </ul>
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>• 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: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the patient's medical record.</li> <li>• Report via organisation incident policy.</li> <li>• 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 <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> for further information</li> </ul>
<b>Written information and further advice to be given to individual</b>	<ul style="list-style-type: none"> <li>• Provide patient information leaflet (PIL) provided with the original pack.</li> <li>• Explain mode of action, side effects, risks and benefits of the medicine</li> <li>• Advise about the risks of the medication including failure rates and serious side effects and the actions to be taken.</li> <li>• Advise about the possible symptoms of serious sequelae, e.g. infection, ectopic pregnancy, expulsion and perforation and when to seek clinical advice</li> <li>• 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</li> <li>• Teach individual how to check threads and to seek clinical advice if threads not felt</li> <li>• Advise when replacement of the LNG-IUD will be due.</li> <li>• Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs)</li> <li>• Ensure the individual has contact details of local service/sexual health services.</li> </ul>
<b>Advice / follow up treatment</b>	<ul style="list-style-type: none"> <li>• The individual should be advised to seek medical advice in the event of an adverse reaction.</li> <li>• Individual to seek further advice if they have any concerns.</li> </ul>

<p><b>Records</b></p>	<p><b>Record:</b></p> <ul style="list-style-type: none"> <li>• The consent of the individual and <ul style="list-style-type: none"> <li>○ If individual is under 13 years of age record action taken</li> <li>○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.</li> <li>○ If individual over 16 years of age and not competent, record action taken</li> </ul> </li> <li>• Name of individual, address, date of birth</li> <li>• GP contact details where appropriate</li> <li>• Relevant past and present medical history, including medication and family history.</li> <li>• Any known allergies</li> <li>• Details of insertion procedure to include: <ul style="list-style-type: none"> <li>○ Name of registered health professional</li> <li>○ Date of insertion</li> <li>○ Name/brand of LNG-IUD inserted</li> <li>○ Batch number and expiry date of product in line with local procedure</li> <li>○ Bimanual examination and speculum findings</li> <li>○ Uterine sounding</li> <li>○ Use of no touch technique</li> <li>○ Name of assistant/their role</li> <li>○ Analgesia or local anaesthetic used</li> <li>○ Problems encountered during insertion</li> </ul> </li> <li>• Advice given, including advice given if excluded or declines treatment</li> <li>• Individual has been advised on the date/s for next appointment as required.</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns</li> <li>• Any referral arrangements made</li> <li>• 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).</li> <li>• Recorded that administration is via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p>
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	<p>An electronic/HEPMA record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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#### 4. Key references

<p><b>Key references</b> (accessed November 2023, February 2024, May 2024)</p>	<ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• NICE Medicines practice guideline "Patient Group Directions" <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• FSRH Clinical Guideline: Intrauterine contraception (March 2023) <a href="https://www.fsrh.org/documents/ceuguidanceintrauterinecontraception/">https://www.fsrh.org/documents/ceuguidanceintrauterinecontraception/</a></li> <li>• Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 <a href="https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/">https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/</a></li> <li>• Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use. <a href="https://www.fsrh.org/documents/ukmec-2016/">https://www.fsrh.org/documents/ukmec-2016/</a></li> <li>• Faculty of Sexual and Reproductive Healthcare (2016) Clinical Guideline: Quick Starting Contraception (April 2017) <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/</a></li> <li>• Faculty of Sexual and Reproductive Healthcare (2019) Service standards for record keeping <a href="https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-record-keeping-july-2019/">https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-record-keeping-july-2019/</a></li> <li>• Faculty of Sexual and Reproductive Healthcare (2023). Response to new study on use of combined and progestogen-only hormonal contraception and breast cancer risk. <a href="#">FSRH Response to new study on use of CHC and POC and breast cancer risk (March 2023) - Faculty of Sexual and Reproductive Healthcare</a></li> </ul>
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	<ul style="list-style-type: none"><li>• FSRH CEU Statement: Extended use of all 52mg LNG-IUDs for up to eight years for contraception (May 2024)</li><li>• <a href="#"><u>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</u></a></li></ul>
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## **Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction**

**I:** \_\_\_\_\_ (Insert name)

**Working within:** \_\_\_\_\_ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

### **Patient Group Direction For Insertion Of The Progestogen-Only Intra-Uterine Device (LNG-IUD) In NHS Grampian, Orkney And Shetland, Version 2.3**

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

**Signed:** \_\_\_\_\_

**Print Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Profession:** \_\_\_\_\_

**Professional Registration number/PIN:** \_\_\_\_\_



## Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

**The Lead manager/Professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

**The Senior Nurse/Professional** who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

**The Healthcare Professional** that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.

### Patient Group Direction For Insertion Of The Progestogen-Only Intra-Uterine Device (LNG-IUD) In NHS Grampian, Orkney And Shetland, Version 2.3

**Local clinical area(s) where the listed healthcare professionals will operate under this PGD:**

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

**Patient Group Direction For Insertion Of The Progestogen-Only Intra-Uterine Device (LNG-IUD) In NHS Grampian, Orkney And Shetland, Orkney  
Version 2.3**

<b>Name of Healthcare Professional</b>	<b>Signature</b>	<b>Date</b>	<b>Name of Manager</b>	<b>Signature</b>	<b>Date</b>