

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)

### Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception

**in Stoke-on-Trent**

Version Number 4.0

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 3.1	Local update
Version 4.0 June 2024	Updated template in line with national updates

#### PGD DEVELOPMENT GROUP


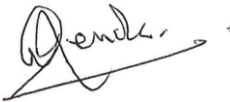
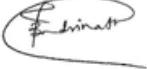
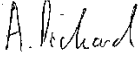


Date PGD template comes into effect:	30th June 2024
Review date:	September 2025
Expiry date:	30 <sup>th</sup> March 2026

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 October 2022.

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

<b>Name</b>	<b>Designation</b>
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
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Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
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Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
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Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

## Stoke-on-Trent Organisational Authorisations

Name	Job title and organisation	Signature	Date
Stephen Gunther	Director of Public Health Stoke-on-Trent City Council		28.06.24
Dr Arabinda Kundu	Consultant/Clinical Lead in Sexual Health, Midlands Partnership Foundation Trust		27.06.24
Dr Padmanabhan Badrinath	Interim Consultant in Public Health Medicine, Stoke-on-Trent City Council		28.06.24
Andrew Pickard	Pharmacy Advisor – NHS Office of the West Midlands		27.06.24
Amin Mitha	Associate Director: Medicines Optimisation Staffordshire and Stoke-on-Trent ICB		27.06.24
Dr Tania Cork	Chief Officer, North Staffordshire and Stoke-on-Trent Local Pharmaceutical Committee		27.06.24

## 1. Characteristics of staff

<b>Qualifications and professional registration</b>	<p>Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p>
<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>Suggested 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.</p> <p>Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - <a href="#">eLfH PGD elearning programme</a></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>
<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 emergency contraception.</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 that 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>• Organisational PGD and/or medication training as required by employing Trust/organisation.</li> </ul>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

## 2. Clinical content of Patient Group Direction for Emergency Hormonal Contraception - Levonorgestrel 1500mcg

<b>Indication</b>	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly.
<b>Aims</b>	To reduce the number of unwanted pregnancies in the City of Stoke-on-Trent through the supply of appropriate emergency hormonal contraception (EHC) to specific individuals by a community pharmacist.
<b>Inclusion Criteria</b>	<p>Individuals should always be advised that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation, is the most effective method of emergency contraception. If the individual is referred on for a Cu-IUD, oral emergency contraception should be given at the time of the referral in case the Cu-IUD cannot be fitted or the individual changes their mind.</p> <ol style="list-style-type: none"> <li>1. Informed consent is given.</li> <li>2. The individual is aged 13 years or over and presents within 96 hours of having sexual intercourse without using contraception or thinks their method of contraception may have failed i.e. Unprotected sexual intercourse, barrier/condom failure, missed pills (refer to current BNF), IUD expulsion, severe diarrhoea and vomiting which may have reduced oral contraception efficacy, allowed &gt;89 days to elapse since the last medroxyprogesterone injection.</li> <li>3. The individual has received Levonorgestrel 1500mcg (LNG-EC) under PGD but has vomited or had severe diarrhoea within 3 hours of the dose (provided still within 96 hours of sexual intercourse).</li> <li>4. Women who are currently taking or have taken an enzyme inducing drug within the past 4 weeks can be offered a double dose LNG-EC (see dose/frequency section). Please refer to the SPC or BNF for full list.</li> <li>5. The individual is either unable or does not wish to attend for an appointment with their GP or Sexual Health Service and is willing to accept the limited service available through the pharmacy. Individuals must always be offered information regarding access to comprehensive contraception and sexual health services available locally.</li> <li>6. The dose may be repeated in the same menstrual cycle should the need occur (but no more than two doses in any given cycle)</li> <li>7. If the individual is excluded for any reason from receiving a supply of Ulipristal Acetate 30mg (UPA-EC) via PGD, a supply of LNG-EC can be considered if the requirements of this PGD are met.</li> </ol> <p>If an individual present within 96 hours of UPSI, and the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation then a supply of UPA-EC via PGD</p>

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	<p>is recommended.</p> <p>As the date of ovulation usually occurs 14 days before the next expected period, individuals with longer menstrual cycles will ovulate later in the cycle.</p> <p><b><i>Under the terms of this PGD it is not possible to give EHC to an individual as a precautionary measure for future need against unprotected sex, neither should it be supplied via a third party.</i></b></p> <p><b><i>Under the terms of this PGD Levonorgestrel is being used off-label in line with national guidelines, Specialist Pharmacy Services and from local experts (senior clinicians and pharmacists).</i></b></p> <p><b><i>Practitioners should consider informing patients or their carers about this off-label use.</i></b></p>
<p><b>Exclusion Criteria</b></p>	<ol style="list-style-type: none"> <li>1. Informed consent not given.</li> <li>2. If this episode of unprotected sexual intercourse occurred <b>more than 96 hours</b>.</li> <li>3. The individual is aged under 13 years - refer to “Supply to young and vulnerable adults” person section for further details.</li> <li>4. Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines.</li> <li>5. The individual is already pregnant, or they think they may be pregnant.</li> <li>6. The individuals last period was late or last period was unusual. (not explained by current hormonal contraception)</li> <li>7. The individual is suffering from abnormal vaginal bleeding (not explained by current hormonal contraception)</li> <li>8. The individual has any known hypersensitivity to the active substance Levonorgestrel or any of the excipients. - see <a href="#">Summary of Product Characteristics</a></li> <li>9. Less than 21 days following child birth</li> <li>10. Less than 5 days following an abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease</li> <li>11. Less than 5 days following ingestion of UPA-EC</li> <li>12. If the individual weighs more than 70kg or has a BMI &gt;26kg/m<sup>2</sup> then UPA-EC should be considered as first line treatment. However, if UPA-EC is not suitable, a double dose of LNG-EC can be given if clinically appropriate</li> <li>13. Acute porphyria</li> </ol> <p><b>Specific medical conditions</b></p> <p>The UKMEC 2016 includes no medical contra-indications to the use of LNG-EC, but referral to a GP or Sexual Health</p>

	<p>Clinic is required in the following circumstances;</p> <ol style="list-style-type: none"> <li>14. The individual is currently suffering from severe liver disease.</li> <li>15. The individual currently has breast cancer or has a previous history of breast cancer</li> <li>16. The individual suffers from an acute severe malabsorption syndrome such as inflammatory bowel disease</li> <li>17. Individuals who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy.)</li> <li>18. The individual suffers from any other medical condition which would be contra-indicated to the supply of (LNG-EC) these include: severe hypertension, uncontrolled diabetes, Lapp lactase deficiency.</li> <li>19. The individual currently has venous thromboembolism (VTE) and is receiving treatment</li> <li>20. The individual has hereditary problems of galactose intolerance or glucose-galactose malabsorption</li> </ol>
<p><b>Supply to young persons and vulnerable adults</b></p>	<p>If a young person (aged &lt;16 years) requests Emergency Contraception, then they must be assessed for competency. If they are deemed as being 'Fraser Competent' then a supply can be made, but this must be documented in the records. If the young person is not deemed to be 'Fraser Competent' advice must be sought from Children's Advice and Duty Service (CHAD) on: <b>01782 235100</b>. Practitioners should discuss with CHAD the remaining need for the child to have access to Emergency Contraception to prevent pregnancy.</p> <p>Further guidance can be found at: <a href="#">Gillick competence and Fraser guidelines   NSPCC Learning</a></p> <p>Pharmacists must be aware of, and comply with the relevant safeguarding expectations from Stoke-on-Trent City Council Safeguarding Board regarding sexual activity in young people:  <a href="https://www.stoke.gov.uk/info/20009/children_and_families/391/stoke-on-trent_safeguarding_children_partnership">https://www.stoke.gov.uk/info/20009/children_and_families/391/stoke-on-trent_safeguarding_children_partnership</a></p> <p>If a child under 13 years requests Emergency Contraception, and there is a reasonable concern that sexual activity has taken place, the pharmacist should contact the CHAD on <b>01782 235100</b> (Monday-Friday 8:30am-6:00pm) and there must be a presumption that the case will be referred to the Children's Social Care Services in the area where the child lives. A record of the referral should be maintained in the pharmacy.</p> <p><b>Children's advice and duty service (CHAD):</b>  Telephone: 01782 235100 (Monday-Friday 8:30am-6:00pm)</p>

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	<p>This is a conversation-based referral service and can be used to discuss concerns even if they do not meet the safeguarding threshold.</p> <p><b>Emergency Duty Team:</b> Telephone: 01782 234234 (after 6pm)</p> <p><b>Stoke-on-Trent City Council Adult safeguarding contact:</b> Telephone: 0800 561 0015 at any time Minicom: 01782 236037</p> <p>For policies and procedures relating to adults, with care and support needs, across Staffordshire please refer to the Staffordshire and Stoke-on-Trent Adult Partnership Board (SSASPB) at <a href="http://Home(ssaspb.org.uk)">Home (ssaspb.org.uk)</a></p> <p>If you think the child, young person or vulnerable adult is in immediate danger, please telephone 999.</p>
<p><b>Management of excluded individuals</b></p>	<ul style="list-style-type: none"> <li>• If the individual falls into the above Exclusion Criteria, LNG-EC cannot be issued.</li> <li>• Explain reason for exclusion and record within PharmOutcomes</li> <li>• If the individual is under 13 years of age, the Pharmacist should follow the local safeguarding procedures as outlined in the ‘Supply to young person’s section’</li> <li>• If the individual is hypersensitive to LNG-EC, refer to their GP or Sexual Health Clinic</li> <li>• If the individual weighs more than 70kg or has a BMI &gt;26kg/m<sup>2</sup>, UPA-EC is recommended. Please refer to UPA-EC PGD. If excluded from UPA-EC, a double dose of LNG-EC can be offered</li> <li>• If the individual is excluded under this PGD, consider making a supply via the UPA-EC PGD if clinically appropriate, or refer to their GP or Sexual Health Clinic.</li> </ul>
<p><b>Management of individuals requiring referral</b></p>	<ul style="list-style-type: none"> <li>• If the individual declines treatment via the pharmacy service, then the benefits and risks must be clearly explained</li> <li>• If the individual wishes an emergency Cu-IUD please refer to their GP or Sexual Health Clinic (NB. not all GPs can fit Cu-IUDs). Oral emergency contraception, if appropriate, should be given at the time of the referral in case the Cu-IUD cannot be fitted or the individual changes their mind.</li> <li>• Where an individual’s date of ovulation cannot be accurately determined, a supply of oral emergency hormonal contraception can only be made if;</li> <li>• the pharmacist deems that it is in the best interests of the individual to receive a supply, and;</li> <li>• the individual is specifically advised that post ovulation, oral emergency hormonal contraception may not be effective, and that further advice should be</li> </ul>

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	<p>sought from their GP or Sexual Health Clinic</p> <ul style="list-style-type: none"> <li>• Advise the individual of alternative sources of treatment, and provide relevant information as appropriate.</li> <li>• Advice given to individuals who require a referral must be recorded within PharmOutcomes</li> </ul>
<b>Reasons for seeking further advice from GP or Sexual Health Service</b>	<ul style="list-style-type: none"> <li>• Any condition/scenario where the pharmacist is uncertain whether a supply should be made</li> <li>• The individual fulfils the exclusion criteria</li> <li>• Breast Cancer</li> <li>• Individuals declining treatment via the pharmacy service</li> </ul>

### 3. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	Levonorgestrel 1500 micrograms tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
<b>Legal category</b>	P/POM
<b>Route of administration</b>	Oral
<b>Dose/Frequency/Duration of Treatment</b>	<p>Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of unprotected intercourse.</p> <p>LNG-EC can be supplied more than once in the same menstrual cycle should the need occur and it is clinically safe to do so.</p> <p>If the individual vomits or has severe diarrhoea within 3 hours of taking the tablet, another tablet should be taken, as long as this is within 96 hours of UPSI.</p> <p>Dose for those individuals taking enzyme inducing medications or herbal products:</p> <ul style="list-style-type: none"> <li>• An individual who requests LNG-EC whilst using enzyme inducing drugs or within 4 weeks of stopping them, should be advised to take a total of 3mg LNG-EC (two 1.5mg tablets) as a single dose</li> </ul> <p>Dose for those individuals with BMI <math>\geq 26\text{kg/m}^2</math> or weight over 70kg:</p> <ul style="list-style-type: none"> <li>• These individuals may be advised to take a total of 3mg LNG-EC (two 1.5mg tablets) as a single dose if excluded from UPA-EC PGD</li> </ul> <p>Individuals should be reminded that a double dose of LNG-EC is less effective than having a Cu-IUD fitted.</p>
<b>Quantity to be supplied</b>	<ul style="list-style-type: none"> <li>• 1 tablet (1 pack)</li> <li>• 2 tablets (2 packs) can be supplied as a single dose for individuals if clinically indicated, e.g. taking enzyme</li> </ul>

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	<p>inducing drugs and/or individuals with a BMI of more than 26kg/m<sup>2</sup> or who weigh more than 70kg.</p>
<b>Cautions</b>	<p><b>Potential drug interactions:</b></p> <ul style="list-style-type: none"> <li>• The metabolism of LNG-EC is enhanced by concomitant use of liver enzyme inducers.</li> <li>• Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin.</li> <li>• Medicines containing LNG-EC may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism.</li> </ul> <p><b>Please refer to current BNF <a href="http://bnf.org/bnf/">http://bnf.org/bnf/</a> and SPC for full details <a href="http://www.medicines.org.uk/emc/">http://www.medicines.org.uk/emc/</a></b></p> <p><b>Pregnancy</b> If pregnancy occurs after treatment with LNG-EC, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as LNG-EC prevents ovulation and fertilisation. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding.</p> <p><b>Breast Feeding</b> Women who breastfeed should be informed that available limited evidence indicates that LNG-EC has no adverse effects on breastfeeding or on their infants. LNG-EC is secreted into breast milk and therefore potential exposure of the infant to LNG-EC can be reduced if the woman takes the tablet immediately after feeding and avoids nursing for at least 8 hours.</p> <p><a href="https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/">https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/</a></p> <p><b>Individuals for whom ovulation has already occurred within the current cycle</b> Women should be advised that oral emergency contraception administered after ovulation is unlikely to be effective. If the individual's ovulation date cannot be determined, or if there is any likelihood that ovulation has already occurred supply of oral emergency hormonal contraception can only be made if the pharmacist deems that it is in the best interests of the individual to receive a supply, and the individual is specifically advised that post ovulation, oral emergency hormonal contraception may not be effective.</p>
<b>Side Effects</b>	<p>Individuals may experience:</p> <ul style="list-style-type: none"> <li>- Nausea and vomiting</li> <li>- Breast tenderness</li> <li>- Headache</li> </ul>

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	<ul style="list-style-type: none"> <li>- Dizziness</li> <li>- Fatigue</li> <li>- Lower abdominal pain</li> </ul> <p>Bleeding patterns maybe temporarily disturbed but most women will have their next menstrual period within 7 days of the expected time. If the next menstrual is more than 5 days overdue, pregnancy should be excluded.</p> <p><b>Please refer to current BNF <a href="http://bnf.org/bnf/">http://bnf.org/bnf/</a> and SPC for full details <a href="http://www.medicines.org.uk/emc/">http://www.medicines.org.uk/emc/</a></b></p> <p>All drug adverse reactions must be reported to MHRA via the <a href="#">Yellow Card System</a>. An individual presenting with a suspected serious adverse drug reaction (ADR) should be referred to their GP.</p>
<p><b>Management of and reporting procedure for adverse reactions</b></p>	<ul style="list-style-type: none"> <li>• Healthcare professionals and individuals 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 individual's medical record.</li> <li>• Report any adverse reactions via organisation incident policy.</li> </ul>
<p><b>Advice/follow up treatment</b></p>	<ul style="list-style-type: none"> <li>• All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation remains the most effective method of emergency contraception, and can be used post-ovulation</li> <li>• Oral emergency hormonal contraception may not be effective post ovulation (see cautions)</li> <li>• Patient Information Leaflets should be highlighted and given to all women supplied with LNG-EC</li> <li>• Provide details of local guide to Sexual Health services.</li> <li>• Individuals who vomit or have severe diarrhoea within 3 hours of taking LNG-EC should be advised to return to the pharmacy or visit their GP or Sexual Health Clinic. If the replacement dose would be later than 96 hours after unprotected intercourse, referral for a Cu-IUD or supply of UPA-EC via PGD may be indicated and the tablets should not be issued.</li> <li>• Advise the individual that her period may arrive earlier, on time or later than usual, that her period may be lighter or heavier and that this supply only treats this episode of unprotected intercourse.</li> <li>• Individuals who have no period within 3 weeks of taking LNG-EC or if the next period is more than 7 days late or abnormal in any way should go to their GP or Sexual Health Clinic to check they are not pregnant.</li> <li>• Emphasise that these tablets are for emergency use only</li> </ul>

	<p>and not as a regular method of contraception, because it is not as effective as regular contraception. Advise that use of emergency contraception does not replace the necessary precautions against sexually transmitted infections.</p> <ul style="list-style-type: none"> <li>• If any abnormal bleeding or pain in days following taking LNG-EC the individual should be advised to contact her GP. The overall risk of ectopic pregnancy following LNG-EC does not appear to be increased; however case reports of such incidents have been documented. There is insufficient post-marketing data to allow accurate assessment of risk. Clinicians and women should be alert to marketing the possibility but the risk is likely to be small.</li> <li>• Individuals who receive LNG-EC should be advised to visit either a GP or Sexual Health Clinic to discuss their further contraceptive needs. Contraception can now be “quick started” following EHC i.e. started immediately rather than waiting until next period.</li> <li>• If the individual is on the oral contraceptive pill, then this should be taken again within 12 hours of taking LNG-EC. Condoms should be used for any intercourse within the next 7 days if using combined oral contraceptive pill, or for 2 days if using progestogen only pill.</li> <li>• Advise individuals taking oral diabetic drugs and insulin that they may find their sugar levels change due to taking LNG-EC but for a short time only</li> </ul> <p><b>Please refer to current BNF <a href="http://bnf.org/bnf/">http://bnf.org/bnf/</a> or SPC for full details <a href="http://www.medicines.org.uk/emc/">http://www.medicines.org.uk/emc/</a></b></p>
<p><b>Records</b></p>	<p>Record: Enter details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation.</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> <li>○ Records should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old.</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 history. Examination finding where relevant e.g. weight</li> <li>• Any known drug allergies</li> <li>• Name of registered health professional operating under</li> </ul>

	<p>the PGD</p> <ul style="list-style-type: none"> <li>• Name of medication supplied</li> <li>• Date of supply</li> <li>• Dose supplied</li> <li>• Quantity supplied including batch number and expiry date in line with local procedures.</li> <li>• Advice given, including advice given if excluded or declines treatment</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. If a safeguarding referral is made, a record of the referral must be maintained in the pharmacy</li> <li>• Any supply outside the terms of the product marketing authorisation</li> <li>• Recorded that supplied via Patient Group Direction (PGD)</li> <li>• If the individual is excluded, a record of the reason for exclusion must be documented and any specific advice given.</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> <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. Additional Information for Individuals before supply

<b>Mode of Action</b>	Unknown but thought to work by preventing ovulation and fertilisation by altering tubal transport of sperm and/or ova. It may also cause endometrial changes that discourage implantation. This means it stops pregnancy before it starts.
<b>Risks</b>	LNG-EC has been found to be less effective the longer it is taken after the UPSI
<b>If already Pregnant</b>	If pregnancy is not prevented consensus of opinion is that LNG-EC will not have an effect on the foetus. However a normal pregnancy as in any other situation cannot be guaranteed.
<b>Adverse Effects</b>	<ul style="list-style-type: none"> <li>• Nausea in up to 1 in 7 women and 1 in 100 are actually sick</li> <li>• Individuals should be advised to return if they vomit within 3 hours of taking the dose because the treatment will not be effective and they should obtain an additional</li> </ul>

	<p>supply</p> <ul style="list-style-type: none"> <li>• Changes to pattern of menstrual bleeding (period may be early or late)</li> <li>• If treatment fails, there is an increased risk of ectopic pregnancy. Advise client to contact GP/ Sexual Health Clinic for further investigation.</li> <li>• Occasionally tender breasts, headaches, dizziness or tiredness</li> </ul>
<b>Advice until next period</b>	Pharmacist to stress that this only provides contraception for one episode. Individuals need to either abstain from sexual intercourse or use barrier method for the remainder of the cycle unless currently using oral contraception (refer to section – advice to patients).
<b>Date last reviewed: June 2024</b>	<b>Date for next review: September 2025</b>
<b>Expiry Date: 30<sup>th</sup> March 2026</b>	<b>Version No: 4.0/ 2024</b>

## 5. References and Glossary

<p><b>Key references</b></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>• Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - March 2017 (Amended March 2020) <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/</a></li> <li>• FSRH CEU Statement Response to Edelman 2022 (August 2022) <a href="https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-response-to-edelman-2022-august-2022/">https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-response-to-edelman-2022-august-2022/</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>• Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 <a href="https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines">https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines</a></li> </ul>
<p><b>Glossary</b></p>	<p>LNG-EC Levonorgestrel 1500mcg tablet            UPA-EC Ulipristal Acetate 30mg tablet            BNF – British National Formulary            SPC – Summary of Product Characteristics            PIL – Patient Information Leaflet            PGD – Patient Group Direction            FSRH – Faculty Sexual &amp; Reproductive Health            UKMEC – UK Medical Eligibility for Contraceptive Use</p>

## 6. Register of practitioners qualified to supply Levonorgestrel 1500mcg via PGD

Operation of this PGD is the responsibility of the commissioner and service providers.

The practitioner must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments, and provided with updated documentation for use by individual practitioners.

Stoke-on-Trent City Council authorise this PGD for use by accredited Community Pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by Stoke on Trent City Council.

This page must be completed and retained by each individual Pharmacist who intends to work in accordance with this PGD.

### Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

<b>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.</b>			
<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

**PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**

Reference Number: 4.0/2024  
Valid from: 30<sup>th</sup> June 2024  
Review date: September 2025  
Expiry date: 30<sup>th</sup> March 2026