PATIENT GROUP DIRECTION (PGD)

Supply of levonorgestrel 1.5mg tablet(s) for emergency contraception by Community Pharmacists and Pharmacy Technicians in England working in a pharmacy registered to provide the NHS Pharmacy Contraception Service

Version 1.0

Change History	
Version and Date	**Change details**
Version 1.0 20 June 2025	PGD approved

This PGD must only be used by pharmacists and pharmacy technicians 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.

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PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	29 October 2025
Review date:	September 2028
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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 November 2022.

The Faculty of Sexual and Reproductive Healthcare (FSRH) has now changed its name to the College of Sexual and Reproductive Healthcare (CoSRH). Some pages and documents will continue to display the FSRH name. Where you see FSRH, this refers to CoSRH.

Name	Designation
Dr Cindy Farmer	Chair General Training Committee; College of Sexual and Reproductive Healthcare (CoSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee; College of Sexual and Reproductive Healthcare (CoSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices

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)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service (SPS)
Sandra Wolper	Associate Director SPS
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms SPS

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ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor **Claire Fuller**	National Medical Director, NHS England		20/06/2025
Senior pharmacist **David Webb**	Chief Pharmaceutical Officer, NHS England		20/06/2025
Person signing on behalf of authorising body **David Webb**	Chief Pharmaceutical Officer, NHS England		20/06/2025

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each pharmacist or pharmacy technician to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual pharmacists or pharmacy technicians must declare that they have read and understood the Patient Group Direction and agree to supply medication(s) listed only in accordance with the PGD.

1. Characteristics of staff

Qualifications and professional registration	GPhC Registered pharmacist or pharmacy technician able to practice under Patient Group Directions (PGDs).
Initial training	The pharmacist or pharmacy technician authorised to operate under this PGD must have undertaken appropriate education and training and be competent to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with the specification. To deliver this service, the pharmacist or pharmacy technician should have evidence of competence in the clinical skills and knowledge covered in the CPPE and/or the NHS England e-learning for healthcare (elfh) modules listed in the **NHS Pharmacy Contraception Service specification.** The pharmacist or pharmacy technician has completed training and is up to date with service requirements for safeguarding children and vulnerable adults.
Competency assessment	• Pharmacists and pharmacy technicians operating under this PGD must have declared their competence and be authorised by a manager within their organization to provide the service (see **Appendix A**). • Pharmacists and pharmacy technicians operating under this PGD are encouraged to review their competency using appropriate competency framework tools, such as the **NICE Competency Framework for health professionals using patient group directions.**
Ongoing training and competency	• Pharmacists and pharmacy technicians 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 undertaken, as required.
The decision to supply any medication rests with the individual pharmacist or pharmacy technician 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	• This PGD applies to the NHS Pharmacy Contraception Service only: To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly.
Criteria for inclusion	• Any individual presenting for emergency contraception (EC) between 0 and 96 hours following UPSI or when regular contraception has been compromised or used incorrectly. • If vomiting has occurred within three hours of taking oral EC.
Criteria for exclusion	• Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • This episode of UPSI occurred more than 96 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 96 hours. • Known pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy

	test if more than three weeks after UPSI and no normal menstrual period since UPSI). • Less than 21 days after childbirth. • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). • Known hypersensitivity to the active ingredient or to any component of the product - see **Summary of Product Characteristics (SPC).** • Use of ulipristal acetate emergency contraception (UPA-EC) in the previous 5 days. • Acute porphyria. • Requests for provision of oral EC in advance as a just in case option.
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 the local safeguarding lead and follow the local safeguarding policy. • If there are reasons to believe an individual aged 16 years of age or over lacks capacity, an assessment of capacity to consent should be conducted and recorded in their notes. Particular consideration should be given to any concern of sexual assault or sexual violence in vulnerable adults. • If the individual has not yet reached menarche, consider onward referral for further assessment or investigation. • All individuals should be informed 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 EC. • Levonorgestrel emergency contraception (LNG-EC) is ineffective if taken after ovulation. • **If a Cu-IUD is appropriate and acceptable, supply oral EC and refer to the appropriate health service provider.** • UPA-EC can delay ovulation until closer to the time of ovulation than LNG-EC and is more effective than

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	LNG-EC because it works closer to the time of ovulation. **Consider UPA-EC if the individual presents in the five days leading up to estimated day of ovulation.** • If an individual vomits within three hours from ingestion of oral EC, a repeat dose may be given. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them - see dose and frequency of administration (below). • Body Mass Index (BMI) >26kg/m^2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. If LNG-EC is to be given, see dose and frequency of administration (below). • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of LNG-EC is not contra-indicated it may be less effective and, so, these individuals should be advised that insertion of a Cu-IUD would be the most effective EC for them and referred accordingly if agreed. • If contraception has been used incorrectly or has been compromised, EC may be indicated. Refer to **CoSRH EC** guidelines (4.3 - Table 1) for additional guidance.
Action to be taken if the individual is excluded or declines treatment	• If excluded, explain the reasons for exclusion to the individual and document in the clinical record. • If the individual declines the recommended EC, record the reason(s) for declining the supply in the clinical record. • Offer suitable alternative EC, or where required, refer the individual as soon as possible 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 1500 micrograms tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
Legal category	P/POM
Route of administration	Oral
Off label use	Best practice advice given by CoSRH is used for guidance in this PGD and may vary from the SPC. This PGD includes off-label use in the following conditions: ○ Use between 72 and 96 hours post UPSI. ○ Consideration of increased dose for individuals with BMI over 26kg/m2or weight over 70kg. ○ Increased dose for individuals using liver enzyme inducing agents ○ Severe hepatic impairment ○ Individuals with previous salpingitis or ectopic pregnancy ○ Lapp-lactase deficiency ○ Hereditary problems of galactose intolerance ○ Glucose-galactose malabsorption Note some products may be licenced only for certain age groups (e.g. 16 years and over) – supply of these products outside the licensed age groups is permitted under this PGD. Medicines should be stored according to the conditions detailed in the manufacturers' guidance. However, in the event of an inadvertent or unavoidable deviation of these conditions, the Responsible Pharmacist must be consulted. Where medicines have been assessed by a Responsible Pharmacist 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 drugs for use lies with the Responsible Pharmacist. Where a drug is recommended for off-label use consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.

Dose and frequency of administration	• Levonorgestrel 1.5mg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI.
	• Dose for **off-label use** - Levonorgestrel 1.5mg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI **except for:**
	  ○ **Dose for those individuals with a body mass index of more than 26kg/m^2 or who weigh more than 70kg:** An individual who requests LNG-EC with a body mass index of more than 26kg/m^2 or who weighs more than 70kg can be offered a total of 3mg LNG-EC (two 1.5mg tablets) as a single dose and within 96 hours of UPSI. **Note:** the effectiveness of this regimen is unknown.
	  ○ **Dose for those individuals taking enzyme inducing medicines or herbal products:** An individual who requests LNG-EC whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1.5mg tablets) as a single dose and within 96 hours of UPSI. **Note:** the effectiveness of this regimen is unknown.

Duration of treatment	• A single dose is permitted under this PGD. • If vomiting occurs within 3 hours of LNG-EC being taken, a repeat dose can be supplied under this PGD as a separate episode of care. • Repeated doses, as separate episodes of care, can be given within the same cycle. Please note:

	○ If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC) ○ If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC)
Quantity to be supplied	• Appropriately labelled pack of one tablet. • Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m^2 or who weigh more than 70kg.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: **https://www.medicines.org.uk/emc** or the BNF **www.bnf.org.** Refer also to Refer also to **CoSRH guidance on drug interactions with hormonal contraception.**
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 following adverse effects are common with LNG-EC (but may not reflect all reported adverse effects): • Nausea and vomiting • Headache • Dizziness • Fatigue • Low abdominal pain • Breast tenderness • Diarrhoea The CoSRH advises that bleeding patterns may be temporarily disturbed, and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time.

Management of and reporting procedure for adverse reactions	• Record all adverse drug reactions (ADRs) in the individual's medical record. • Pharmacists, pharmacy technicians and individual's/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme: http://yellowcard.mhra.gov.uk
Management of and reporting procedure for patient safety incidents	• The pharmacy is required to report any patient safety incidents in line with the https://www.gov.uk/government/publications/clinical-governance-approved-particulars.
Written information and further advice to be provided	• All methods of EC should be discussed. • All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of EC. • Provide a patient information leaflet (PIL with the original pack. • If vomiting occurs within three hours of taking the dose, the individual should be advised to return for another dose. • Explain that menstrual disturbances can occur after the use of oral EC. • Provide advice on ongoing contraceptive methods, including how these can be accessed. • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. • Explain oral EC methods do not provide ongoing contraception. • Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Advise after oral EC, there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle.

	• Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. • Where appropriate promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. • Advise there is no evidence of harm if someone becomes pregnant in a cycle when they had used oral EC. • Advise to consult a pharmacist, pharmacy technician, nurse or doctor before taking any new medicines or herbal products, including those purchased. • Where an individual is breastfeeding, advise levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the individual takes the tablet immediately after feeding and avoids nursing for at least eight hours following levonorgestrel administration. • Provide the individual with the results of any biometrics and measurements undertaken where relevant e.g. weight, height, BMI.
Advice/follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to the individual above). • Individuals should be advised how to access on-going contraception and STI screening as required.
Records	Record: • The consent of the individual and ○ If individual is under 13 years of age, record action taken.

Publication reference: PRN02207
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	○ If individual is under 16 years of age, document capacity using Fraser guidelines. If not competent, record action taken. ○ If individual is over 16 years of age and not competent, record action taken. • Name of individual, address, date of birth. • GP contact details where appropriate. • Reason for EC request: UPSI / regular contraception has been compromised / regular contraception used incorrectly / vomiting has occurred within three hours of taking oral EC • Relevant past and present medical and sexual history, including medication history (to include over the counter, herbal medications, supplements and recreational drug use). • Results of biometrics and measurements where relevant e.g. weight, height and BMI. • Any known allergies and nature of reaction. • Name and registration number of pharmacist or pharmacy technician. • Name of medication supplied. • Date of supply. • Dose amount. • Quantity supplied. • Where two tablets supplied, reason: BMI > 26kg/m2 / weigh more than 70kg / taking enzyme inducing drugs. • Advice given, including advice given and action taken if excluded or declines treatment. • 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 supply outside the terms of the product marketing authorisation (off-label use). • Recorded that supplied via PGD.

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Version: 1.0
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	Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with the specification. 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 the specification.

4. Key references

Key references (accessed September 2022)	• NHS Pharmacy Contraception Service Specification : https://www.england.nhs.uk/long-read/nhs-pharmacy-contraception-service/ • Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • FSRH Clinical Guidance: Emergency Contraception - March 2017 (Amended July 2023) https://www.cosrh.org/Public/Documents/ceu-clinical-guidance-emergency-contraception-march-2017.aspx • FSRH CEU Statement: Response to Edelman 2022 (August 2022) https://www.cosrh.org/Public/Documents/fsrh-ceu-statement-response-to-edelman-2022-august-2022.aspx • FSRH CEU Guidance: Drug Interactions with Hormonal Contraception – May 2022 https://www.cosrh.org/Public/Documents/ceu-clinical-guidance-drug-interactions-with-hormonal.aspx

	• Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines

Appendix A - Registered pharmacist and pharmacy technician authorisation sheet

PGD Levonorgestrel (LNG) Version 1.0

Valid from: 29 October 2025 **Expiry: 28 February 2029**

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

Registered pharmacist or pharmacy technician

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

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each pharmacist or pharmacy technician 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 PGD 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 pharmacists and pharmacy technicians named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above-named pharmacists and pharmacy technicians 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 pharmacists and pharmacy technicians to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those pharmacists and pharmacy technicians authorised to work under this PGD.