Patient Group Direction (PGD) for supply and/or administration of:

Levonorgestrel 1500 microgram tablet(s) for Emergency Contraception

The content of this PGD has been taken from the national template created by the Specialist Pharmacy Service (SPS) and the Faculty of Sexual and Reproductive Health (FSRH) and adopted for use within County Durham and Darlington NHS Foundation Trust

1. CHARACTERISTICS OF STAFF

Qualifications and Professional Registration

Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.

Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.

Initial Training

The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with local policy.

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.

Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme

The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.

Competency Assessment

- Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence for emergency contraception.
- Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions

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Ongoing Training and Competency
• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation. • The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.

2. CLINICAL CONDITION OR SITUATION TO WHICH THIS PGD APPLIES

Clinical condition or situation to which this PGD applies

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.
- No contraindications to the medication.
- Informed consent given.

Criteria for Exclusion

- Informed consent not given.
- 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
- Use of ulipristal acetate (UPA-EC) emergency contraception in the previous 5 days.
- Acute porphyria.

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Cautions Including any Relevant Action to be Taken

- 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 emergency contraception. 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 levonorgestrel (LNG-EC). Consider UPA-EC if the individual presents in the five days leading up to estimated day of ovulation.
- LNG-EC is ineffective if taken after ovulation.
- If individual vomits within three hours from ingestion, a repeat dose may be given.
- Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them - see dose frequency section.
- 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 dosage section.
- 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 Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed.
- If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.
- If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy.

  If the individual has not yet reached menarche consider onward referral for further assessment or investigation.

Action to be Taken if the Individual is Excluded or Declines Treatment

- Explain the reasons for exclusion to the individual and document in the consultation record.
- Record reason for decline in the consultation record.
- Offer suitable alternative emergency contraception or 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 (this is equivalent to 1.5mg levonorgestrel)

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Legal Category
P / POM
Route of Administration
Oral
Off Label Use

Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (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 Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs 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 drugs for use lies with pharmacy/Medicines Management.

Where a drug is recommended off-label 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.

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Dose and Frequency of Administration

- Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI.
- **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 1500mcg tablets) as a single dose and within 96 hours of UPSI. **Note** the effectiveness of this regimen is unknown.
- **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 1500mcg 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.
- 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.

Storage

Medicines must be stored securely according to national guidelines and in accordance with the product SPC.

Drug Interactions

A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org

Refer also to FSRH guidance on drug interactions with hormonal contraception

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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 side effects are common with LNG-EC (but may not reflect all reported side effects):

- Nausea and vomiting are the most common side effects.
- Headache, dizziness, fatigue, low abdominal pain and breast tenderness, diarrhoea.
  The FSRH 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

- 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: http://yellowcard.mhra.gov.uk
- Record all adverse drug reactions (ADRs) in the individual's medical record.
- Report any adverse reactions via organisation incident policy.

Written Information and Further Advice to be Given to Individual

- All methods of emergency contraception 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 emergency contraception.
- Ensure that a patient information leaflet (PIL) is provided within the original pack.
- If vomiting occurs within three hours of taking the dose, the individual should return for another dose.
- Explain that menstrual disturbances can occur after the use of emergency hormonal contraception.
- 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.
- 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 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.
- Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs.
- There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
- Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased.

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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 individual above).
- Individuals 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
  - if individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
  - if individual over 16 years of age and not competent, record action taken
- Name of individual, address, date of birth
- GP contact details where appropriate
- Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight
- Any known drug allergies
- Name of registered health professional operating under the PGD
- Name of medication supplied
- Date of supply
- Dose supplied
- Quantity supplied including batch number and expiry date in line with local procedures.
- Advice given, including advice given 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
- Recorded that supplied via Patient Group Direction (PGD)

Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.

All records should be clear, legible and contemporaneous.

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. KEY REFERENCES *(Accessed January 2024)*

- Electronic Medicines Compendium
  http://www.medicines.org.uk/
- Electronic BNF
  https://bnf.nice.org.uk/
- NICE Medicines practice guideline "Patient Group Directions"
  https://www.nice.org.uk/guidance/mpg2
- Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - March 2017 (Amended March 2020)
  https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/
- 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/
- Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022
  https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
- 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

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PGD Development Group

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.

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
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
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

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Change History	
Version and Date	**Change Details**
Version 1.0 March 2020	New template
Version 1.1 November 2020	Addition of acute porphyria added to exclusion criteria.
Version 2.0 March 2023	Updated template (no clinical changes to expired v1.0)

Date National PGD Template comes into effect	1 March 2023
Review Date	1 September 2025
Expiry Date	28 February 2026

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This Patient Group Direction must be agreed to and signed by all Healthcare Professionals involved in its use

The NHS Trust should hold the original signed copy

The PGD must be easily accessible in the clinical setting

This PGD has been approved for use in County Durham & Darlington NHS Foundation Trust by:

Name	*Position*	*Signed*	*Date*
Lead Pharmacist:			
Christine McCartney	Lead Pharmacist – Family Health	[redacted]	21.08.2024
Lead Doctor:			
Dr Susan Ralph	Consultant in Genito-Urinary Medicine, Contraception & Sexual Health	[redacted]	21.08.2024
Lead Nurse:			
Pam Murgatroyd	Matron for Sexual Health Services	[redacted]	21.08.2024
Clinical Standards & Therapeutics Committee:			
Dr Shafie Kamaruddin	Chair of Clinical Standards and Therapeutics Committee	[redacted]	21.08.2024

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PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY
PGDs should be used in conjunction with reference to national or local policies, guidelines or standard text (eg. Manufacturers Summary of Product Characteristics) and do not replace the need to refer to such sources.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance to their own Code of Professional Conduct.

Declaration by Healthcare Professional

- **I have read and understood the Patient Group Direction and agree to supply/administer medicine only in accordance with the PGD**
- **I understand that this PGD can only be used to supply and/or administer the specified medication to an individual patient if they fully meet the inclusion criteria.**
- **I confirm I meet the required staff characteristics specified in this PGD.**
- **I confirm I have read the Trust Patient Group Direction Policy.**

PRINT NAME of Healthcare Professional	***SIGNATURE of Healthcare Professional***	***Date***
Job Title	***Service/Department***	

Declaration by Authorising Manager

- **I confirm the above named Healthcare Professional has been authorised to work under this PGD.**
- **I confirm the Healthcare Professional fulfils the staff characteristics specified in this PGD.**
- **I confirm the Healthcare Professional has been supplied with a full copy of this PGD including clinical content and authorisation.**
- **I confirm I have a copy of the full PGD signed by myself and the Healthcare Professional, which will be retained for future audit.**

PRINT NAME of Authorising Manager	***SIGNATURE of Authorising Manager***	***Date***
Designation	***Service/Department***	