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 must be used.

PATIENT GROUP DIRECTION (PGD)

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

in Accredited Warwickshire Community Pharmacies by an Accredited Pharmacist

Version Number 1.2

Change History	
Version and Date	**Change details**
Version 1 March 2020	New template – national template circulated for local use.
Version 1.1 June 2020	Information included to use the template in Warwickshire.
Version 1.2 July 2022	Information review as renewal is due November 2022

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

Subject to all the conditions and criteria below, this Patient Group Direction allows an accredited pharmacist in an accredited pharmacy to supply for the pharmacy, appropriately packaged, the named drug to patients for self-administration without the need for a prescription from a doctor. The pharmacist must have completed the specified additional training and confirm via the declaration of competency that they are professionally competent to operate and agree to work within this Patient Group Direction.

Valid from: November 2022
Expiry date: November 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	November 2022
Review date	July 2024
Expiry date:	November 2024

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 2019.

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

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

Valid from: November 2022
Expiry date: November 2024

Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Samrina Bhatti	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS - WARWICKSHIRE

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Cristina Ramos Chair & Director South Warwickshire GP Federation		30/08/2022
Senior pharmacist	Mahesh Mistry Deputy Director Clinical Services NHS Arden and Greater East Midlands Commissioning Support Unit		18/08/2022
Senior representative of professional group using the PGD			
Person signing on behalf of authorising body			

1. Characteristics of staff

Valid from: November 2022
Expiry date: November 2024

Qualifications and professional registration	Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation. Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC), who are working in a pharmacy contracted to NHS England (Warwickshire). Provider pharmacists to have enhanced level DBS status.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. 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 advised in the RCN training directory. 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 the supply of emergency contraception (see Appendix A). They must recognise and work within the limitations of their own individual competencies and scope of practice. The Pharmacist should be able to demonstrate the competencies specified in NICE's Competency Framework for Health Professionals using Patient Group Directions. NICE Competency Framework for health professionals using patient group directions. Delegation of responsibility is not permissible under PGD legislation. Levonorgestrel may only be supplied by the authorised pharmacist who has clinically assessed the patient under the guidance of this PGD.
Ongoing training and competency	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 undertaken as required. The pharmacist must maintain a regular self-assessment declaration of competency every two years or sooner if appropriate. Organisational PGD and/or medication training as required by the employing Trust/organisation

The decision to supply 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	Provision of emergency hormonal contraception (EHC) to women within a 72-96-hour period of unprotected sexual intercourse (UPSI) which may include suspected failure of a contraceptive method.
Objectives	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or if regular contraception has been compromised.
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. **Note:** Levonorgestrel can be given in women presenting between 72-96 hours of UPSI (off-label recommendation from BNF and FSRH) for whom ulipristal acetate is either inappropriate or unavailable AND although an IUD has been recommended it is either refused or thought unlikely to be complied with. Use between 72-96 hours is outside the terms of the product license but is in line with clinical best-practice. • No contraindications to the medication. • Informed consent given. • Severe diarrhoea and/or vomiting which may have reduced oral contraceptive efficacy. NHS guidance suggests continued vomiting or diarrhoea for more than 24hrs could reduce protection against pregnancy. • Treated previously with levonorgestrel in the same cycle. **<u>Special notes on age</u>** You may still supply the medication if it is in the best interests of the patient. **All patients under 18 years:** A risk assessment should be undertaken to determine whether the child is at risk of

	harm. If you have a concern, the matter should be discussed with the local safeguarding lead. **All patients under 16 years:** Must be competent as assessed under the Fraser Guidelines on consent to medical treatment. **All patients under 13 years:** The matter must be discussed with the local safeguarding lead. You may still supply the medication if it is in the best interests of the patient. **The pharmacist must be aware of their local safeguarding contact numbers for adults and children.**
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. • Individuals unable to attend in person. • Acute active porphyria. • Acute trophoblastic disease – seek specialist advice. • This episode of UPSI occurred more than 96 hours ago. **Note:** 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 or suspected 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 **Note:** Check for any drug interactions. Use of ulipristal acetate emergency contraception in the previous 5 days.
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 levonorgestrel and refer the patient to the appropriate health service provider. • If the last period was more than 4 weeks ago then a pregnancy test should be performed. • Ulipristal acetate can delay ovulation until closer to the

	time of ovulation than levonorgestrel. Consider ulipristal if the individual presents in the five days leading up to estimated day of ovulation. • Levonorgestrel 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/m2 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 EHC. If levonorgestrel 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 levonorgestrel 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. • Contraceptive efficacy can be reduced when the woman is currently taking or within 28 days of stopping griseofulvin and the following hepatic enzyme inducing medicines: anti-epileptics (e.g. carbamazepine, eslicarbazepine, oxcarbazepine, topiramate, phenobarbital, phenytoin, primidone, rufinamide); anti-TB drugs (e.g. rifampicin, rifabutin); anti-retrovirals (e.g. ritonavir efavirenz, nelfinavir, nevirapine); antidepressants (e.g. St John's Wort –a herbal preparation); others (e.g. aprepitant, modafinil,bosentan). In this case, the woman should be offered a Cu-IUD which is considered more effective in this context. **However, if the pharmacist feels that the suggestion of an IUD is unlikely to be acted upon, a higher dose (3 mg) can be offered instead.** For more information on drug interaction, see the latest BNF and FSRH Drug Interactions with Hormonal Contraception. • Unexplained vaginal bleeding. • 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. Following termination of pregnancy, consider the date of termination as the last menstrual period.
Action to be taken if the individual is excluded or declines treatment	• Discuss and document why the client is excluded from the service. • Offer suitable alternative emergency contraception or refer the individual without undue delay to a suitable healthcare service provider if appropriate and/or provide them with information about further options. • Consider supply and administration of ulipristal acetate if clinically appropriate (refer to ulipristal PGD). • Discuss and document the reasons why the patient has declined treatment. Advise the patient that a delay in starting treatment may compromise its efficacy.

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. **Administration while the patient is present should be encouraged and supported, although this is voluntary.** If the tablet is not taken in the pharmacy, the woman should be advised to take it as soon as possible.
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. ○ Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg and in individuals using liver enzyme inducing agent. It is recommended that a double dose (3 mg) of levonorgestrel is given where ulipristal acetate is contraindicated or unavailable. ○ Severe hepatic impairment. ○ Individuals with previous salpingitis or ectopic pregnancy. ○ Lapp-lactase deficiency. ○ Hereditary problems of galactose intolerance. ○ Glucose-galactose malabsorption. 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.
Dose and frequency of administration	• Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI. • If vomiting occurs within THREE hours of taking the tablet, a second tablet should be taken immediately. • **Dose for those individuals taking enzyme inducing medicines or herbal products:** An individual who requests levonorgestrel whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, should be advised to take a total of 3 mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. **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 levonorgestrel with a body mass index of more than 26kg/m^2 or who weighs more than 70kg, can be offered a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI.
Duration of treatment	• A single dose is permitted under this PGD. • If vomiting occurs within 3hrs of taking levonorgestrel a repeat dose can be supplied. • Repeated doses can be given within the same cycle. Please note: ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal). If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel).
Quantity to be supplied	• Appropriately labelled pack of one tablet. Two tablets should be supplied for individuals taking enzyme inducing drugs 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
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 levonorgestrel (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 provided	• 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.
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. • Make individual aware that this is for emergency contraception only and should not from part of on-going contraception. • Provide three condoms to the client wherever appropriate. • Explain other available treatment option including a Cu-IUD. • Advise patient that she could still become pregnant. If next period is delayed by more than 7 days or is abnormal in any way (light, heavy or painful), woman should seek medical advice. • There is no evidence to date that the hormones used post coitally carry any risk of teratogenicity should the method fail, and a pregnancy occur • Seek medical advice if the patient experiences severe lower abdominal pain as this could signify an ectopic pregnancy. • According to FSRH, the use of levonorgestrel is not contraindicated during breastfeeding. The SPC for Levonelle ® advises that levonorgestrel is secreted into breast milk and that potential exposure of the infant to levonorgestrel can be reduced if the woman takes the tablet immediately after feeding and avoids nursing for at least 8 hours. However, studies report no evidence of an adverse effect on the infant or on lactation and that women can be advised to continue to breastfeed after using levonorgestrel. For individuals who are reluctant to comply with this, the option of having an IUD should be discussed as an alternative. Emergency contraception is an occasional method. It should in no instance replace a regular method of contraception.
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. ○ A “Fraser Ruling Assessment of Competency” form must be completed for all women under 16 years of age. • 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. • GPhC number and name of pharmacist who administered or supplied the medication and provided the consultation. Name of medication supplied. • Date of supply. • Dose supplied. • Quantity supplied. • Brand, batch number and expiry date • 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

Key references (accessed August 2022)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2020 Updated December 2018 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception –May 2022 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 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 health professional authorisation sheet

LEVONORGESTREL EHC Valid from: November 2022 Expiry: November 2024

Version 1.2

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

Registered health professional

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

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

A copy of each person's Declaration of Competency has been submitted to Warwickshire County Council via CSW-Jets(Intend). Checks will be undertaken by WCC to ensure up to date documents are available to view to enable payment against activity.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Warwickshire County Council for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**
Helen Earp	Sexual Health Commissioner Warwickshire County Council		??/??/22

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.