PATIENT GROUP DIRECTION (PGD)

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

By registered pharmacists for

Emergency Hormonal Contraception In Community Pharmacy

Version Control

This document is only valid on the day it was printed. The most recent and in date final version of the PGD must be used.

The current version of this document can be found on Pharmoutcomes and the LPC website here

Version	Date	Author	Change description
Version 1.0	March 2024	Shola Olowosale	New template

Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

The authorising body accepts governance responsibility for the appropriate use of the PGD.

Shropshire Council and Telford and Wrekin Council authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Sexual health services provided by community pharmacies commissioned by Shropshire Council and Telford and Wrekin Council
Limitation to authorisation
The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of their self-declaration and sign up to the current PGD

Authorisation

This document requires authorisation by the following individuals:

Management			
PGD Author	Shola Olowosale Clinical Pharmacist NHS Shropshire Telford and Wrekin Integrated Care Board		
Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Rachel Robinson Statutory Director of Public Health	Shropshire Council		25/03/2024
Liz Noakes Statutory Director of Public Health	Telford and Wrekin Council		25/03/2024
Arabinda Kundu Consultant/Clinical Lead in Sexual Health	Midlands Partnership Foundation Trust		26/03/2024
Elizabeth Walker Deputy Director Medicines Management	NHS Shropshire Telford and Wrekin Integrated Care Board		22/03/2024

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.

1. Characteristics of staff

Qualifications and professional registration	Pharmacist with current General Pharmaceutical Council registration Work in a Community Pharmacy within Shropshire Council, or Telford and Wrekin Council. Pharmacist is required to have suitable indemnity insurance.
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 the service specification 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 complete the self-declaration form appropriate to this PGD, as detailed in the CPPE and NHS Health Education England *Declaration of Competence for pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* ▪ Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
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 provided as required. ▪ Individuals operating under this PGD must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction*
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 situationto 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.

Supply to young persons	▪ If a young person (aged <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. ▪ Pharmacists must use their professional judgement when considering 'Safeguarding' issues related to sexual activity in young persons. ▪ If a child under 13 years requests Emergency Contraception, and there is a reasonable concern that sexual activity has taken place, the pharmacist should always contact: **Family Connect Telford - 01952 385385 or 01952676500 (Out of Hours)** **Shropshire Family Information Service- 01743254400** ▪ There must always 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. The pharmacy may also adopt: Regional Child Protection Procedures for West Midlands If you think the child or young person is in immediate danger telephone 999
Cautions including any relevant actions 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 productsor 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
Management of excluded individuals	▪ If the individual falls into the above Exclusion Criteria, LNG-EC cannot be issued. ▪ Explain reason for exclusion and record within PharmOutcomes. ▪ 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'. ▪ If the individual is hypersensitive to LNG-EC, refer to their GP or Sexual Health Clinic ▪ If the individual weighs more than 70kg or has a BMI >26kg/m^2, UPA-EC is recommended. Please refer to UPA-EC PGD. If excluded from UPA-EC, a double dose of LNG-EC can be offered. ▪ 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.
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
Management of individuals requiring referral	▪ If the individual declines treatment via the pharmacy service, then the benefits and risks must be clearly explained. ▪ 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. ▪ Where an individual's date of ovulation cannot be accurately determined, a 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, and that further advice should be sought from their

	GP or Sexual Health Clinic ▪ Advise the individual of alternative sources of treatment and provide relevant information as appropriate. ▪ Advice given to individuals who require a referral must be recorded within PharmOutcomes.
Reasons for seeking further advice from GP or Sexual Health Service	▪ Any condition/scenario where the pharmacist is uncertain whether a supply should be made. ▪ The individual fulfils the exclusion criteria. ▪ Breast Cancer ▪ Individuals declining treatment via the pharmacy service

3. Description of treatment

Name, strength & formulationof drug	Levonorgestrel 1500 micrograms tablet (N.B. this isequivalent to 1.5mg levonorgestrel)
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 thisPGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off-label use in the following conditions: o use between 72- and 96-hours post UPSI o consideration of increased dose for individuals with BMI over 26kg/m²or weight over 70kg o increased dose for individuals using liver enzyme inducing agents o severe hepatic impairment o individuals with previous salpingitis or ectopic pregnancy o lapp-lactase deficiency o hereditary problems of galactose intolerance o glucose-galactose malabsorption Note some products may be licensed 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 license.
Dose and frequency ofadministration	▪ 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.

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/m² 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
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 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. ▪ Advise to consult a pharmacist, nurse, or doctor before taking any new medicines including those purchased.
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.
Supply	Individuals are required to take LNG-EC in the pharmacy. They should be provided with the patient information leaflet and local guide to the Sexual Health Clinic. Shropshire Sexual Health Clinic Tel No——————— Telford and Wrekin Sexual Health Clinic Tel No. 0300 123 0994 Website http://openclinic.org.uk/clinics/?contract=1 All individuals, whether supplied with EHC or not should be given the local guide to Sexual Health Services.

Records	Record: ▪ In discussion with the individual, enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. ▪ Informed verbal consent should be obtained (for individuals aged under 16 years, Fraser guidelines should be followed) o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. o If individual over 16 years of age and not competent, record action taken. ▪ If LNG-EC is to be supplied then the Pharmacist asks the individual to sign only when the Pharmacist is confident that the individual understands the information she has been given. ▪ Electronic patient records and/or the completed paper proforma should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records are recommended to be kept. ▪ If the individual is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. ▪ If a safeguarding referral is made, a record of the referral must be maintained in the pharmacy.

4. Key references

Key references (accessed September 2022)	▪ 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
Glossary	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 & Reproductive Health UKMEC – UK Medical Eligibility for Contraceptive Use

Appendix A – example registered health professional authorisation sheet

PGD Name/Version **Valid from:** **Expiry:**

Before signing this PGD, check that the document has had the necessary 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.

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 insert name of organisation for the above-named health care professionals 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 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.
Add details on how this information is to be retained according to organisation PGD policy.