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

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 http://www.southstaffslpc.co.uk/services/emergency-hormonal-contraception/

Revision History

Version	Date	Author	Change description
3.1 / 2022	Feb 2022	Andrew Pickard	Local update

Authorisation
This document requires authorisation by the following individuals:

Management			
PGD Author	Andrew Pickard, Pharmacy Advisor - NHS England & Improvement Midlands (Staffordshire and Shropshire)		
Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Richard Harling – Lead Doctor	Staffordshire County Council		30/03/2022
Andrew Pickard Pharmacy Advisor	NHS England & Improvement Midlands		07/03/2022
Dr Arabinda Kundu Consultant/Clinical Director in Sexual Health	Midlands Partnership Foundation Trust		15/03/2022

Specialist advice			
Dr Arabinda Kundu Consultant / Clinical Director in Sexual Health	Midlands Partnership Foundation Trust		15/03/22

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

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	• Community pharmacists authorised by Central Health Solutions under contract to Staffordshire County Council via the EHC Service Specification to provide an Emergency Contraception Service.
2. Competencies required to be held by staff undertaking this PGD	• Have a clear understanding of the legal requirements to operate a PGD. Patient group directions (nice.org.uk) • Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself. • Have a clear understanding of the drug to be administered including side effects and contraindications. • Individuals operating under this PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.
3. Specialist qualifications, training, experience and competence considered relevant to the clinical condition treated under this PGD	• The community pharmacist must be registered with the General Pharmaceutical Council • Completion of the current CPPE training packages on Emergency Contraception Emergency contraception : CPPE and Safeguarding Vulnerable Adults and Children Safeguarding children and adults at risk: a guide for the pharmacy team : CPPE • Completion of the CPPE learning pack – Combating CSE: An e-learning resource for healthcare professionals is required Combatting CSE - An e-learning resource for healthcare professionals: CPPE • Attendance at a local training event(s) approved by Staffordshire County Council is recommended where these are organised, but this is not a prerequisite for delivering this service.

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR EMERGENCY HORMONAL CONTRACEPTION Levonorgestrel 1500mcg

Clinical Details	
Indication	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or when regular contraception has been compromised or used incorrectly.
Aims	To reduce the number of unwanted pregnancies in Staffordshire by the supply of appropriate emergency hormonal contraception (EHC) to specific individuals by a community pharmacist.
Inclusion Criteria	Individuals should always be advised that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation, is the most effective method of emergency contraception. If the individual is referred on for a Cu-IUD, oral emergency contraception should be given at the time of the referral in case the Cu-IUD cannot be fitted or the individual changes their mind. 1. Informed consent is given. 2. The individual is aged 13 years or over and presents within 72 hours of having sexual intercourse without using contraception or thinks their method of contraception may have failed i.e. Unprotected sexual intercourse, barrier/condom failure, missed pills (refer to current BNF), IUD expulsion, severe diarrhoea and vomiting which may have reduced oral contraception efficacy, allowed >89 days to elapse since the last medroxyprogesterone injection. 3. The individual has received Levonorgestrel 1500mcg (LNG-EC) under PGD but has vomited or had severe diarrhoea within 3 hours of the dose (provided still within 72 hours of sexual intercourse). 4. Women who are currently taking or have taken an enzyme inducing drug within the past 4 weeks can be offered a double dose LNG-EC (see dose/frequency section). Please refer to the SPC or BNF for full list. 5. The individual is either unable or does not wish to attend for an appointment with their GP or Sexual Health Service and is willing to accept the limited service available through the pharmacy. Individuals must always be offered information regarding access to comprehensive contraception and sexual health services available locally. 6. The dose may be repeated in the same menstrual cycle should the need occur (but no more than two doses in any given cycle)

	7. If the individual is excluded for any reason from receiving a supply of Ulipristal Acetate 30mg (UPA-EC) via PGD, a supply of LNG-EC can be considered if the requirements of this PGD are met. If an individual presents within 72 hours of UPSI, and the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation then a supply of UPA-EC via PGD is recommended. As the date of ovulation usually occurs 14 days before the next expected period, individuals with longer menstrual cycles will ovulate later in the cycle. Under the terms of this PGD it is not possible to give EHC to an individual as a precautionary measure for future need against unprotected sex, neither should it be supplied via a third party.
Exclusion Criteria	1. Informed consent not given. 2. If more than 72 hours after unprotected sexual intercourse. 3. The individual is aged under 13 years 4. Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. 5. The individual is already pregnant, or they think they may be pregnant. 6. The individuals last period was late or last period was unusual. (not explained by current hormonal contraception) 7. The individual is suffering from abnormal vaginal bleeding. (not explained by current hormonal contraception) 8. The individual has any known hypersensitivity to the active substance Levonorgestrel or any of the excipients. 9. Less than 21 days following child birth 10. Less than 5 days following an abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease 11. Less than 5 days following ingestion of UPA-EC 12. If the individual weighs more than 70kg or has a BMI >26kg/m^2 then UPA-EC should be considered as first line treatment. However, if UPA-EC is not suitable, a double dose of LNG-EC can be given if clinically appropriate **Specific medical conditions** The UKMEC 2016 includes no medical contra-indications to the

	use of LNG-EC, but referral to a GP or Sexual Health Clinic is required in the following circumstances; 13. Acute porphyria 14. The individual is currently suffering from severe liver disease. 15. The individual currently has breast cancer or has a previous history of breast cancer 16. The individual suffers from an acute severe malabsorption syndrome such as inflammatory bowel disease 17. Individuals who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy.) 18. The individual suffers from any other medical condition which would be contra-indicated to the supply of (LNG-EC) these include: severe hypertension, uncontrolled diabetes, Lapp lactase deficiency. 19. The individual currently has venous thromboembolism (VTE) and is receiving treatment 20. Please note, LNG-EC contains lactose and as such it is recommended that consideration is given between the pharmacist and the individual as to whether a referral to a GP or Sexual Health Clinic would be most appropriate.
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. If the young person is not deemed to be 'Fraser Competent' advice must be sought from First Response Team on: 0800 1313126 (or the Emergency Duty Team on 0345 6042886 outside of office hours). Practitioners should discuss with First Response the remaining need for the child to have access to Emergency Contraception to prevent pregnancy. Further guidance can be found at: Gillick competence and Fraser guidelines | NSPCC Learning Pharmacists must be aware of, and comply with the relevant safeguarding expectations from Staffordshire Safeguarding Board regarding sexual activity in young people: Safeguarding Practice Guidance - Staffordshire Safeguarding Children Board (staffsscb.org.uk) 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 the First Response

	team on 0800 1313 126 (or the Emergency Duty Team on 0345 6042886 outside of office hours) and 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. If you think the child or young person is in immediate danger telephone 999
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.

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

Drug Details	
Name, form & strength of medicine	Levonorgestrel 1500 microgram tablet (LNG-EC)
Legal classification	Prescription Only Medicine (POM)
Route/Method	Oral
Dosage/Frequency/ Duration of Treatment	One tablet of LNG-EC as a single dose as soon as possible, preferably within 12 hours and no later than 72 hours after unprotected intercourse. LNG-EC can be supplied more than once in the same menstrual cycle should the need occur and it is clinically safe to do so. If the individual vomits or has severe diarrhoea within 3 hours of taking the tablet, another tablet should be taken, as long as this is within 72 hours of UPSI. Dose for those individuals taking enzyme inducing medications or herbal products: • An individual who requests LNG-EC whilst using enzyme inducing drugs or within 4 weeks of stopping them, should be advised to take a total of 3mg LNG-EC (two 1.5mg tablets) as a single dose Dose for those individuals with BMI ≥26kg/m^2 or weight over 70kg: • These individuals may be advised to take a total of 3mg LNG-EC (two 1.5mg tablets) as a single dose if excluded from UPA-EC PGD Individuals should be reminded that a double dose of LNG-EC is less effective than having a Cu-IUD fitted.
Quantity to supply/administer	• 1 tablet (1 pack) • If clinically indicated, 2 tablets (2 packs) may be supplied as a single dose

Cautions	**Potential drug interactions:** • The metabolism of LNG-EC is enhanced by concomitant use of liver enzyme inducers. • Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin. • Medicines containing LNG-EC may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism. **Please refer to current BNF** http://bnf.org/bnf/ **and SPC for full details** http://www.medicines.org.uk/emc/ **Pregnancy** If pregnancy occurs after treatment with LNG-EC, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as LNG-EC prevents ovulation and fertilisation. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding. **Breast Feeding** Women who breastfeed should be informed that available limited evidence indicates that LNG-EC has no adverse effects on breastfeeding or on their infants. LNG-EC is secreted into breast milk and therefore potential exposure of the infant to LNG-EC can be reduced if the woman takes the tablet immediately after feeding and avoids nursing for at least 8 hours. https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ **Individuals for whom ovulation has already occurred within the current cycle** Women should be advised that oral emergency contraception administered after ovulation is unlikely to be effective. If the individual's ovulation date cannot be determined, or if there is any likelihood that ovulation has already occurred supply of oral emergency hormonal contraception can only be made if the pharmacist deems that it is in the best interests of the individual to receive a supply, and the individual is specifically advised that post ovulation, oral emergency hormonal contraception may not be effective.
Side Effects	Individuals may experience: • Nausea and vomiting • Breast tenderness • Headache

	• Dizziness • Fatigue Bleeding patterns maybe temporarily disturbed but most women will have their next menstrual period within 7 days of the expected time. If the next menstrual is more than 5 days overdue, pregnancy should be excluded. **Please refer to current BNF** http://bnf.org/bnf/ **and SPC for full details** http://www.medicines.org.uk/emc/ Use the Yellow Card System to report adverse drug reactions directly to the MHRA. Yellow Cards and guidance are available at the back of the BNF. http://yellowcard.mhra.gov.uk/
Advice/follow up treatment	• All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation remains the most effective method of emergency contraception, and can be used post-ovulation • Oral emergency hormonal contraception may not be effective post ovulation (see cautions) • Patient Information Leaflets should be highlighted and given to all women supplied with LNG-EC • Provide details of local guide to Sexual Health services. • Individuals who vomit or have severe diarrhoea within 3 hours of taking LNG-EC should be advised to return to the pharmacy or visit their GP or Sexual Health Clinic. If the replacement dose would be later than 72 hours after unprotected intercourse, referral for an Cu-IUD or supply of UPA-EC via PGD may be indicated and the tablets should not be issued. • Advise the individual that her period may arrive earlier, on time or later than usual, that her period may be lighter or heavier and that this supply only treats this episode of unprotected intercourse. • Individuals who have no period within 3 weeks of taking LNG-EC or if the next period is more than 7 days late or abnormal in any way should go to their GP or Sexual Health Clinic to check they are not pregnant. • Emphasise that these tablets are for emergency use only and not as a regular method of contraception, because it is not as effective as regular contraception. Advise that use of emergency contraception does not replace the necessary precautions against sexually transmitted infections. • If any abnormal bleeding or pain in days following taking LNG-EC the individual should be advised to contact her GP. The overall risk of ectopic pregnancy following LNG-EC does not appear to be increased; however case reports of such incidents have been documented. There is insufficient post-marketing data to allow accurate

	assessment of risk. Clinicians and women should be alert to marketing the possibility but the risk is likely to be small. • Individuals who receive LNG-EC should be advised to visit either a GP or Sexual Health Clinic to discuss their further contraceptive needs. Contraception can now be "quick started" following EHC i.e. started immediately rather than waiting until next period. • If the individual is on the oral contraceptive pill, then this should be taken again within 12 hours of taking LNG-EC. Condoms should be used for any intercourse within the next 7 days if using combined oral contraceptive pill, or for 2 days if using progestogen only pill. • Advise individuals taking oral diabetic drugs and insulin that they may find their sugar levels change due to taking LNG-EC but for a short time only **Please refer to current BNF** http://bnf.org/bnf/ **or SPC for full details** http://www.medicines.org.uk/emc/

Additional information for individuals before supply

Mode of Action	Unknown but thought to work by preventing ovulation and fertilisation by altering tubal transport of sperm and/or ova. It may also cause endometrial changes that discourage implantation. This means it stops pregnancy before it starts.
Risks	LNG-EC has been found to be less effective the longer it is taken after the UPSI
If already pregnant	If pregnancy is not prevented consensus of opinion is that LNG-EC will not have an effect on the foetus. However a normal pregnancy as in any other situation cannot be guaranteed.
Adverse effects	• Nausea in up to 1 in 7 women and 1 in 100 are actually sick • Individuals should be advised to return if they vomit within 3 hours of taking the dose because the treatment will not be effective and they should obtain an additional supply • Changes to pattern of menstrual bleeding (period may be early or late) • If treatment fails, there is an increased risk of ectopic pregnancy. Advise client to contact GP/ Sexual Health Clinic for further investigation. • Occasionally tender breasts, headaches, dizziness or tiredness

Advice until next period	Pharmacist to stress that this only provides contraception for one episode. Individuals need to either abstain from sexual intercourse or use barrier method for the remainder of the cycle unless currently using oral contraception (refer to section – advice to patients).

Records and Follow Up	
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. Sexual Health Clinics in Staffordshire are run by Midlands Partnership NHS Foundation Trust (MPFT) To find out opening times in north Staffordshire (districts of Newcastle under Lyme and Staffordshire Moorlands) Telephone: 0300 7900 165 To find out opening times in southern Staffordshire (districts of Cannock, East Staffordshire, Lichfield, South Staffordshire, Stafford and Tamworth Telephone 0300 124 5022 Alternatively, opening times for MPFT clinics across Staffordshire can be found here: Home - Open Clinic All individuals, whether supplied with EHC or not should be given the local guide to Sexual Health Services.
Records/audit trail	• 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) • 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

Adverse drug reactions	All serious adverse reactions must be reported to MHRA via the yellow card system www.yellowcard.gov.uk. An individual presenting with a suspected serious ADR should be referred to their GP.
Date last reviewed: February 2022	**Date for next review: February 2024**
Expiry date: 31st March 2024	**Version No: 3.1 / 2022**

References	Electronic Medicines Compendium - Home - electronic medicines compendium (emc) Electronic BNF - BNF British National Formulary - NICE FSRH – Clinical Guidance Emergency Contraception (amended Dec 2017) - FSRH Clinical Guideline: Emergency Contraception (March 2017, amended December 2020) - Faculty of Sexual and Reproductive Healthcare
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

Register of practitioners qualified to supply Levonorgestrel 1500mcg via PGD

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

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

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

Central Health Solutions under contract to Staffordshire County Council authorise this PGD for use by accredited Community Pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by Central Health Solutions.

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

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- I 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 of professional (please print)	Signature	Date of signing

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY