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

Version Control

This document is only valid on the day it was printed

The current version of this document will be found on the appropriate PharmOutcomes module, and on the Staffordshire LPC website:
http://www.southstaffslpc.co.uk/services/emergency-hormonal-contraception/

Revision History

Date of this revision: November 2019
Date of next revision: Sept 2021 (or in response to new local/national guidelines)

Version	Date	Author	Change description
1.1 / 2017	Sept 2017	Andrew Pickard	N/A
2.1 / 2019	Nov 2019	Andrew Pickard	• Inclusion criteria • Exclusion criteria • Management of excluded clients • Dose/Frequency/Duration • Quantity to supply

Authorisation

This document requires authorisation by the following individuals:

Management	
PGD Author	Andrew Pickard, Pharmacy Advisor – NHSE&I Midlands (Staffordshire and Shropshire)

Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Richard Harling – Lead Doctor	Staffordshire County Council		20/12/2019
Antony Bullock – Lead Commissioner	Staffordshire County Council		19/12/2019
Andrew Pickard - Pharmacy Advisor	NHS England North Midlands		20/11/2019

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

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	• Community pharmacists accredited by the Prime Provider of the contract with Staffordshire County Council to provide an Emergency Hormonal Contraception Service.
2. Competencies required to be held by staff undertaking this PGD	• Has a clear understanding of the legal requirements to operate a PGD. • Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself. • Has a clear understanding of the drug to be administered including side effects and contraindications. • All clinicians operating within the 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, and have completed the current CPPE training packages on Emergency Contraception and Safeguarding Vulnerable Adults and Children. • Completion of the CPPE learning pack - Combating CSE: An e-learning resource for healthcare professionals. • Attendance at a local training event(s) approved by Staffordshire Council is recommended where these are organised, but this is not a prerequisite for delivering the service.

Clinical Details	
Indication	Postcoital Emergency Contraception

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	Clients should always be advised that the Cu-IUD is the most effective method of emergency contraception. If the client 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 client changes their mind. 1. The client 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. 2. Client has received Levonorgestrel (LNG-EC) 1500mcg under PGD but has vomited within 3 hours of the dose (provided still within 72 hours of sexual intercourse). 3. Women who are currently taking or have taken an enzyme inducing drug within the past 4 weeks can be offered a double dose of LNG-EC (see dose/frequency section). These include rifampicin, carbamazepine, ciclosporin, warfarin, griseofulvin, primidone, phenobarbital, phenytoin, topiramate, ritonavir, St.Johns Wort – refer to BNF for full list. 4. The client 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. Clients must always be offered information regarding access to comprehensive contraception and sexual health services available locally. 5. The dose may be repeated in the same menstrual cycle should the need occur (but no more than two doses in any given cycle) 6. If the client is excluded for any reason from receiving a supply of Ulipristal Acetate 30mg (UPA-EC) via PGD, a supply of Levonorgestrel can be considered if the requirements of this PGD are met. If a client 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, clients with longer menstrual cycles will ovulate later in the cycle.

	Under the terms of this PGD it is not possible to give EHC to women as a precautionary measure for future need against unprotected sex, neither should it be supplied via a third party.
Exclusion Criteria	1. If more than 72 hours after unprotected sexual intercourse. 2. The client is deemed not competent as defined in the Fraser Guidance 1985. 3. The client is already pregnant or they think they may be pregnant. 4. The clients last period was late or last period was unusual. (not explained by current hormonal contraception) 5. The client is suffering from abnormal vaginal bleeding. (not explained by current hormonal contraception) 6. The client has any known hypersensitivity to the active substance Levonorgestrel or any of the excipients. 7. Less than 21 days following child birth 8. Less than 5 days following an abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease 9. Less than 5 days following ingestion of UPA-EC 10. If the client 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 recommended in the following circumstances; 11. Active Acute Porphyria 12. The client is currently suffering from severe liver disease. 13. The client currently has breast cancer. 14. The client suffers from Crohn's Disease or other severe malabsorption syndrome. 15. Patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy. 16. The client is aware of any other medical reason why she should not take emergency contraception (LNG-EC) these include: severe hypertension, uncontrolled diabetes , hereditary problems of galactose intolerance, Lapp lactase deficiency.
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 be aware of and comply with the relevant safeguarding expectations from Staffordshire Safeguarding Board regarding sexual activity in young people https://www.staffsscb.org.uk/Professionals/Procedures/Section-

	Four/Section-Four-Docs/Section-4J-Sexually-Active-Children-and-Young-People-Guidance-Final-September-2017.doc If a child under 13 years requests Emergency Contraception, then supply can be made, but as there is reasonable concern that sexual activity has taken place, the pharmacist must contact the First Response team on 0800 1313 126 (or the Emergency Duty Team on 0845 6042886 outside of office hours)
Management of excluded clients	• If the client falls into the above Exclusion Criteria, Levonorgestrel 1500mcg cannot be issued. • Explain reason for exclusion and record within PharmOutcomes • If client is more than 72 hours, but less than 120 hours after unprotected intercourse UPA-EC can be offered. Please refer to UPA-EC PGD. • If the client is hypersensitive to LNG-EC, refer to their GP or Sexual Health Clinic • If a client weighs more than 70kg or has a BMI ≥26kg/m2, UPA-EC is recommended. Please refer to UPA-EC PGD. If excluded from UPA-EC PGD, a double dose of LNG-EC can be offered. • If the client is excluded under this PGD, consider making a supply via the UPA-EC PGD if clinically appropriate, or refer client to their GP or Sexual Health Clinic.
Management of patients requiring referral	• If the client declines treatment via the pharmacy service, then the benefits and risks must be clearly explained • If the client 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 client changes their mind. • Where a client'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 client to receive a supply, and; ➢ the client 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 client of alternative sources of treatment, and provide relevant information and contact details as appropriate. • Advice given to clients 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 • Patient fulfils the exclusion criteria • Breast Cancer • Client declining treatment via the pharmacy service

Drug Details	
Name, form & strength of medicine	Levonorgestrel 1500 microgram tablet (LNG)
Legal classification	Prescription Only Medicine (POM)
Route/Method	Oral
Dosage/Frequency/ Duration of Treatment	One tablet of Levonorgestrel 1500 micrograms as a single dose as soon as possible, preferably within 12 hours and no later than 72 hours after unprotected intercourse. Levonorgestrel 1500mcg can be supplied more than once in the same menstrual cycle should the need occur and it is clinically safe to do so. **Dose for those clients taking enzyme inducing medications or herbal products:** • A client 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 clients with a BMI of ≥26kg/m² or weight over 70kg:** • These clients 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.
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 LNG-EC 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. The SPC for Levonelle advises that LNG-EC is secreted into breast milk and that 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/news/fsrh-launches-new-emergency-contraception-guideline/
Side Effects	Patient 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 to patients	• Cu-IUD remains the most effective method of emergency contraception and can be used post-ovulation • Oral emergency hormonal contraception may not be effective post ovulation. • Patient Information Leaflets should be highlighted and given to all women supplied with LNG-EC. • Local guide to Sexual Health services. • Clients 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 IUD or supply via UPA-EC PGD may be indicated and the tablets should not be issued. • Advise client 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. • Clients 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 client 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. • Clients who receive LNG-EC emergency contraception 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 client 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 clients 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 clients 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	**Coitus-to-treatment interval** 0 - 24 hours 0 – 72 hours 0 - 120 hours	**Pregnancy rate** 2.5% 2.2% 2.2%
	Faculty of Sexual & Reproductive Health Care Clinical Guidance (2017) Emergency Contraception	
	If the assessed risk of pregnancy is high (20-30%), the residual risk after LNG-EC may remain unacceptably high for some women. The option of an IUD with its low failure rate may be appropriate even if the woman presents within 72 hours. In such cases LNG-EC may still be supplied under the PGD prior to referral.	
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 actually sick ■ Client 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 fails – risk of ectopic pregnancy, advise client to contact GP/ Sexual Health Clinic to ensure it is not ectopic ■ Occasionally tender breasts, headaches, dizziness or tiredness
Until next period	Pharmacist to stress that this only provides contraception for one episode. Clients 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	Clients 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: http://openclinic.org.uk/

Records/audit trail	• In discussion with the client 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 clients aged under 16 years, Fraser guidelines should be followed) • If LNG-EC emergency contraception is to be supplied then the pharmacist asks the client to sign only when the pharmacist is confident that the client 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 client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given.
Adverse drug reactions	All serious adverse reactions must be reported to MHRA via the yellow card system **www.yellowcard.gov.uk**. A client presenting with a suspected serious ADR should be referred to their GP.

Date last reviewed: November 2019	**Date for next review: September 2021**
Expiry date: 31st December 2021	**Version No: 2.1 / 2019**

References	BNF – Current Version SPC Levonelle 1500 – Bayer Healthcare June 2019 PIL Levonelle 1500 - Bayer Healthcare Sept 2019 FSRH – Clinical Guidance Emergency Contraception (Amended Dec 2017)
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.

Lloyds Pharmacy PLC 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 Lloyds Pharmacy PLC.

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 have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

Name of professional (please print)	Signature	Date of signing

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY