PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF LEVONORGESTREL 1500mcg FOR EMERGENCY CONTRACEPTION BY COMMUNITY PHARMACISTS PROVIDING COMMUNITY PHARMACY PUBLIC HEALTH SERVICES WITHIN NHS LOTHIAN

MANAGEMENT OF PATIENT GROUP DIRECTION

This Patient Group Direction must be read, agreed to and signed by all healthcare professionals involved in its use. The original signed copy should be held by a designated person and must be easily accessible to healthcare professionals in the clinical setting. In all cases the healthcare professional will follow the code of conduct as defined by their professional body.

	Name	Signature	Date
Developed by LOCAL DEVELOPMENT TEAM			
Doctor	Prof. Sharon T Cameron		
Pharmacist	Garry Todd		

Approved by PGD SUB-GROUP OF THE MEDICINES POLICY COMMITTEE			
Chairperson	Garry Todd		

Approved by AUTHORISED NHS LOTHIAN DRUGS AND THERAPEUTICS COMMITTEE			
Chairperson/Deputy of Committee	Dr Emma Morrison		

AUTHORISED BY			
Medical Director	Ms Tracey Gillies		

LOCAL MANAGEMENT			
Practice/Ward/Department/Directorate			
Doctor			
Practitioner Manager (if applicable)			
Pharmacist (if applicable)			
Name of Designated PGD Holder (Responsible for ensuring names of healthcare professionals issuing under this PGD are kept up to date			

DATE AUTHORISED FOR USE	REVIEW DATE	EXPIRY DATE
30/06/2023	30/06/2025	30/06/2026

Contractor Code	
Locum	

AUTHORISED PRACTITIONER LIST:

I have read and understood the Patient Group Direction and agree to use it and acknowledge that it is my responsibility to maintain my knowledge, skills and competencies through CPD.

Name	Signature	GPhC Number	Date

1. CHARACTERISTICS OF STAFF	
Define Practitioner Group	Community Pharmacists providing pharmacy public health services within NHS Lothian.
Qualifications Required	Professional registration with GPhC
Additional requirements	▪ Undertaken appropriate training to carry out clinical assessment of patient leading to the provision of emergency contraception according to the indications listed in this PGD ▪ Undertaken appropriate training for working under PGDs for the supply and administration of medicines ▪ Community pharmacists have undertaken the appropriate NES e-learning modules.. ▪ Able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent
Continued training requirements	As required by NHS Lothian.

2. DESCRIPTION OF TREATMENT	
Names of Medicines included	Levonorgestrel
Marketing Authorisation (previously UK Product Licence)	YES
Outwith terms of the Summary of Product Characteristics	A systematic review has concluded that emergency contraceptives containing LNG or mifepristone (another progesterone receptor modulator not licensed for use in the UK as EC) do not increase the chance that a pregnancy will be ectopic. Moreover, in common with all contraceptive methods, EC reduces the absolute risk of ectopic pregnancy by preventing pregnancy in general. A previous ectopic pregnancy is not a contraindication to use. FSRH advice is that women with a BMI greater than 26kg/m^2 or total body weight greater than 70kg require a double dose of levonorgestrel.
2nd Pharmacist Check	YES
Controlled Drugs **If YES, consultation with CDGT to check legal compliance**	NO
Antibiotic **If YES, consultation with Microbiologist/Antimicrobial Management Team**	NO

Children under 13 years of age to be treated **If YES, consultation with Neonatologist, Paediatrician, Public Health or Unscheduled Care**	NO NO
Record / Audit trail	▪ Assessment form, PMR record ▪ Generic drug name(and brand if appropriate), strength,form,dose,frequency,quantity,batch number and expiry ▪ Professional's printed name,signature and date of supply (or electronic equivalents when using electronic prescribing platforms) ▪ Agreed records maintained according to NHS Lothian policy

3. MEDICINES and CLINICAL CONDITION	
Name of medicine	Levonorgestrel
Define situation/condition	For women who have had unprotected sex or failed contraception within the last 72 hours.
Criteria for inclusion (including patient group)	Women who have had unprotected sex or failed contraception within the last 72 hours and have reached menarche, aged 13-50 years, who have been fully informed about the efficacy, mode of action, advantages, disadvantages, side effects, review of contraceptive requirements and safe sex.
Criteria for exclusion	▪ Under 13 years of age ▪ Not reached menarche ▪ Over 50 years of age ▪ Known hypersensitivity to levonorgestrel or any other component of the medicine ▪ Over 72 hours since unprotected intercourse ▪ Late with last menstrual period • 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. ▪ Unexplained abnormal vaginal bleeding

	▪ Severe malabsorption syndromes including Crohn's Disease ▪ Galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. ▪ Hypersensitivity to the active substance levonorgestrel or any of the excipients ▪ Use of enzyme inducing drugs: – primidone, phenytoin, carbamazepine, barbiturates, rifampicin,rifabutin, griseofulvin (for fungal infection) – Ritonavir (and for 4 weeks after discontinuation) – St John's Wort – Ciclosporin ▪ Severe liver disease ▪ Acute intermittent porphyria ▪ Active trophoblastic disease ▪ Severe diarrhoea and vomiting ▪ Informed non consent ▪ Assessed as not competent to consent treatment (apply Fraser Guidelines to under 16s)
Action if excluded	▪ Refer to authorised prescriber ▪ Document in Medical/electronic Records
Action if patient declines	▪ Refer to authorised prescriber ▪ Document in Medical/electronic Records
Pharmaceutical form and strength of medicine	1500microgram tablet
POM / P / GSL / ▼	POM
Dose/s	≤26kg/m^2 or ≤ 70kg -One 1500 microgram tablet should be taken as soon as possible, preferably within 12 hours of unprotected sex. > 26kg/m^2 or >70kg – Two 1500 microgram tablet should be taken as soon as possible, preferably within 12 hours of unprotected sex
Route/Method	Oral
Frequency (To include maximum/minimum timescales)	≤26kg/m^2 or ≤ 70kg One 1500 microgram tablet only within 72 hours after unprotected sex. It is most effective if taken in the first 12 hours > 26kg/m^2 or >70kg Two 1500 microgram tablets within 72 hours after unprotected sex. It is most effective if taken in the first 12 hours
Total dose/number	One or Two 1500 microgram tablet
Drug interactions and action to be taken	▪ Enzyme inducing drugs such as primidone, phenytoin, carbamazepine, barbiturates, rifampicin, rifabutin, griseofulvin (for fungal infection) ▪ Ritonavir ▪ St John's Wort ▪ Ciclosporin

	Refer to authorised prescriber Refer to BNF for latest information on interactions
Cautions (including action to be taken if caution applies)	• 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. • 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.
Adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected (▼ - include yellow card details)	▪ Side effects such as nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, diarrhoea, irregular spotting ▪ Minimal disruption of menstrual cycle ▪ If a serious adverse reaction is suspected please report to the Commission on Human Medicines (CHM) via the Yellow Card Scheme http://yellowcard.mhra.gov.uk/ ▪ Advise to contact nurse/GP if any side effects occur.
Additional advice and information	▪ Please note that the most effective method of emergency contraception is a copper IUD. This should be discussed with all women. If a woman wishes to have an emergency IUD then she can be referred to Chalmers Centre (Edinburgh) for insertion. The woman can also be given Levonelle prior to attendance for an IUD in case there is any delay or problem with insertion of the IUD ▪ Efficacy, advantages and disadvantages ▪ Mode of action ▪ Method of taking ▪ Women should be advised that oral Emergency Contraception methods do not provide contraceptive cover for subsequent unprotected sexual intercourse and that they will need to use contraception or refrain from sex to avoid further risk of pregnancy • 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. ▪ If a woman is likely to continue to be at risk of pregnancy or has expressed a preference to start contraception immediately after Emergency Contraception, a health

	professional may 'quick start' combined hormonal contraception (excluding co-cyprindiol), the progestogen-only pill (POP) or implant, providing the woman has been appropriately informed and advised to have a pregnancy test in ≥3 weeks ▪ Following administration of levonorgestrel, for women continuing to use a hormonal method, if the woman becomes pregnant, the possibility of an ectopic pregnancy should be considered, particularly for those with a past history of ectopic pregnancy. Women should be advised to seek medical advice or return to the Pharmacy if they vomit within 3 hours of taking levonorgestrel A repeat dose of the same method or a copper intrauterine device may be offered if appropriate. ▪ Give written information leaflet on emergency contraception. Manufacturers Patient Information Leaflet should be offered. ▪ Headache, nausea and altered bleeding patterns are side effects common to oral EC.Nausea is reported by less than 20% of women using LNG EC and vomiting occurs in only 1%. ▪ Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased. Advise to return to pharmacy if vomiting occurs within 3 hours of dose (as another tablet should be taken immediately).

Referral, patient monitoring and follow-up	Women should be advised about menstrual disturbances after oral EC use. If there is any doubt about whether menstruation has occurred, a pregnancy test should be performed ≥3 weeks after UPSI has occurred

4. REFERENCES

Summary of Product Characteristics of Levonelle 1500® last accessed 30/06/2023 via http://www.medicines.org.uk last updated 21/06/18

BNF last accessed 30/06/2023 via https://www.bnf.nice.org.uk

http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf

Cleland K, Raymond E, Trussell J, Cheng L, Zhu H. Ectopic pregnancy and emergency contraceptive pills: a systematic
review. Am J Obstet Gynecol 2010; 115: 1263–1266.