Patient Group Direction

Supply of Levonorgestrel 1500 micrograms by Pharmacists for Emergency Hormonal Contraception
Protocol number 323 Version 7

Date protocol prepared: **July 2022**

Date protocol due for review: **July 2024**

Expiry Date **August 2025**

This patient group direction must be signed by all health care professionals involved in its use. The NHS organisation should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Organisation	NHS Forth Valley

Job Title	Name	Signature	Date
Director of Nursing	Frances Dodd	Signed by Frances Dodd	18/5/23
Medical Director	Andrew Murray	Signed by Andrew Murray	4/5/23
Director of Pharmacy	Laura Byrne	Signed by Laura Byrne	19/5/23

This document authorises the supply of **Levonorgestrel 1500mcg** by appropriate practitioners to patients who meet the criteria for inclusion under the terms of the document.

Practitioners seeking to supply **Levonorgestrel 1500 mcg** must ensure that they assess all patients to make sure they meet the criteria before supplying the product.

The purpose of this Patient Group Direction is to help patients by ensuring that they have ready access to a quality assured service which provides a timely, consistent and appropriate supply of **Levonorgestrel 1500mcg** for **emergency hormonal contraception**.

Signatures of those developing the Patient Group Direction

Job Title	Name	Signature	Date
Doctor	Dr Olga Diaz-Morales	Signed by Olga Diaz-Morales	3/5/23
Pharmacist	Kirstin Cassells	Signed by Kirstin Cassells	23/3/23
Nurse			
Microbiologist (if appropriate)			
Paediatrician (if appropriate)			

Approval from Patient Group Directions Group

	Chair	Signed on behalf of group	Date
Patient Group Directions Group	Laura Byrne	Signed by Laura Byrne	19/5/23

Change history

Version	Date	Summary of changes
7	18/8/2022	Caution/need for further advice section updated to reflect current FSRH guidance where IUD or Ulipristal cannot be offered. Qualifications updated with current template wording References updated to current versions

The following Patient Group Direction for Supply of Levonorgestrel 1500mcgs by Community Pharmacists for emergency hormonal contraception may be used from the following business/practice:

Name:

Address:

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

CLINICAL CONDITION

Indication	Patient presenting in person at the community pharmacy requesting emergency contraception for their own use within 72 hours of unprotected sexual intercourse (UPSI).
Inclusion Criteria	Patient is aged 13 years or over. Unprotected sexual intercourse/contraception failure within the last 72 hours. Unprotected sexual intercourse/contraception failure within the last 72 hours where patient has vomited within 3 hours of taking a dose of levonorgestrel for emergency hormonal contraception. Patient gives their consent to providing the relevant clinical information to the pharmacist after pharmacist has assessed their capacity to consent (see under Staff). (Breastfeeding is not an exclusion)
Exclusion Criteria	Patient is aged 12 years or under. **The Child Protection Team must be contacted for children of 12 years and under, who present having had sexual intercourse.** Patient who the pharmacist has assessed as not being competent to consent. Unexplained vaginal bleeding. Patient has had unprotected sex more than 72 hours ago. Levonorgestrel should not be given to pregnant women. Previous unprotected sexual intercourse in current menstrual cycle. Patient used levonorgestrel for emergency hormonal contraception in current menstrual cycle. (If patient has vomited within 3 hours of taking a dose of levonorgestrel, dose can be repeated. Refer to

	Inclusion Criteria.) Severe hepatic dysfunction. History of salpingitis or ectopic pregnancy. Severe malabsorption syndromes e.g. severe diarrhoea, Crohns disease. Porphyria. Hypersensitivity to levonorgestrel or any of the tablet ingredients/ excipients. Patients who have delivered a baby within last 3 weeks (EHC not required in these circumstances). Patient does not agree to share relevant clinical information or there is no valid consent. Patients with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption as contains lactose.
Caution/ Need for further advice	**Present Faculty of Sexual and Reproductive Healthcare guidelines recommend that if a woman cannot be offered an Intrauterine device (IUD) ; or ulipristal EC; or if ulipristal EC is contra-indicated, then the patient should be informed that the alternative Levonorgestrel EC is slightly less effective than ulipristal EC** **It should be noted that if Levonorgestrel is prescribed in women weighing >70 kg or with a BMI >26 kg/m^{2,,}, a double dose (3 mg) should be given.** In order to maximise the likelihood that Levonorgestrel will work, it is important that it is taken as soon as possible after unprotected intercourse. For Information: Women who breastfeed should be informed that available limited evidence indicates that Levonorgestrel has no adverse effects on breastfeeding or on their infants.
Action if Patient declines or is excluded	All excluded patients should be referred to Sexual Health Service or GP practice. Direct referral process contained within the Unscheduled Care Folder should be used during out of hours period. If unprotected sex was within the last 5 days (120 hours) the patient may be suitable for IUD (intrauterine device) insertion or use of

	Ulipristal. Assessment or referral should be made in a suitable timeframe to allow this to happen. Patient should be advised of the risks of the consequences of not receiving treatment. Record outcome in Patient Medication Record if appropriate. Prior to the supply of Levonorgestrel, consent must be obtained, preferably written, from the patient. Where a patient does not have capacity to consent then this may be provided by a parent, guardian or person with parental responsibility. Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used. Individuals (patient, parent, guardian or person with parental responsibility) should also be informed about how data on the supply will be stored, who will be able to access that information and how that data may be used. A patient under 16 years of age may give consent for the supply of EHC, provided she understands fully the benefits and risks involved. The patient should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the patient indicates that she wishes to accept the supply, supply should proceed, if the pharmacist deems the patient to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2(4) states that 'a person under the age of 16 years shall have legal capacity to consent on her own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending her, she is capable of understanding the nature and possible consequences of the procedure or treatment.' Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical procedure which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure or treatment.

DRUG DETAILS

Name, form & strength of medicine	Levonorgestrel Tablet 1500 microgram (mcg) Store in original container below 25°C
Legal Status	POM
Route/ Method	Oral
Dosage	Female patients of 13 years and over – Take 1500micrograms as a single oral dose as soon as possible after coitus (preferably within 12 hours but no later than 72 hours after the event). If the patient is >70kg or has a BMI >26kg/m² then TWO tablets of levonorgestrel 1500micrograms should be taken as the single dose (total dose 3000micrograms levonorgestrel). This is an unlicensed indication for levonorgestrel not included in the Summary of Product Characteristics (SPC) but is a recommendation of the Faculty of Sexual and Reproductive Healthcare Clinical Guidance on Emergency Contraception. If the patient is using an enzyme-inducing medication or has stopped taking such medication within the last 28 days (see BNF for interacting medications), then TWO tablets of levonorgestrel 1500micrograms should be taken as the single dose (total dose 3000micrograms levonorgestrel). Patients taking enzyme inhibiting medication may experience adverse effects and may require additional monitoring (see interacting medications) If vomiting occurs within 3 hours of taking the original dose, another dose should be taken immediately. 1500micrograms (one tablet) as a single dose, or 3000micrograms (two tablets) as a single dose if patient also taking enzyme-inducing medication or has stopped taking such within last 28 days; or >70kg or has a BMI >26kg/m².
Frequency	Once per menstrual cycle
Duration of treatment	Single oral dose, preferably within 12 hours but no later than 72 hours. If vomiting occurs within 3 hours of taking the original dose, another dose should be taken immediately
Maximum or minimum treatment period	Once per menstrual cycle
Quantity to Supply/ administer	See dosage
Side Effects	For a full list of side effects – refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on www.medicines.org.uk All adverse reactions that are serious or result in harm should be reported to the MHRA through the Yellow Card Scheme.

	https://yellowcard.mhra.gov.uk/
Advice to patient/carer	1. Patient Information Leaflet provided with medication. 2. Written information about locally available contraception services and methods of contraception. 3. Written information about locally available services providing sexual health advice. 4. Pregnancy test in 3 weeks if no withdrawal bleeding The pharmacist must ensure maintenance of records for each supply (For example see appendix 1) and may be required to share information with appropriate parties in line with confidentiality protocols. ***Reduced efficacy of Levonorgestrel*** The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers or use within the last 28 days, and these medications can reduce the efficacy of levonorgestrel. A full list is available in Appendix 1 of the relevant section of the British National Formulary, or in the SPC for the product being used. These include: Anticonvulsants: Barbiturates (including Primidone), Phenytoin, Carbamazepine, Oxcarbazepine, Topiramate . Anti-Fungal: Griseofulvin Anti-Retroviral: Ritonavir Herbal Medicines containing Hypericum perforatum (St. John's wort). Rifamycins: Rifampicin, Rifabutin Endothelin receptor antagonist: Bosentan ***Effect of Levonorgestrel on other medication*** Immunosuppressants: metabolism of ciclosporin reduced (increased plasma concentration). Increased risk of toxicity. Additional monitoring may be required. Caution is advised when prescribing for patients using the anticoagulant drugs, phenindione and warfarin. Anticoagulant effects may be altered following use. Additional monitoring may be required. Patients should be advised about potential drug

	interactions and attention should be paid to their anticoagulation monitoring. Menstrual irregularities, nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting. All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and recorded in the appropriate place (e.g. the Minor Injury Record Sheet or the Allergies and Adverse Reactions section of the Patient Record). Where appropriate a Yellow Card Report will be forwarded to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Online reporting is available at http://yellowcard.mhra.gov.uk/. None. Current NHS exemption is applicable. The Patient's CHI number should be recorded on the CPUS form where available
Follow up	Advise patient to seek medical advice should symptoms worsen or not improve None required.

STAFF CHARACTERISTICS

Qualifications	Pharmacist currently on the practising section of pharmaceutical register held by the General Pharmaceutical Council.
Specialist competencies or Qualifications	The pharmacist must maintain their own level of competence and knowledge in this area to provide the service. Under PGD legislation there can be no delegation. Supply of Levonorgestrel has to be by the same practitioner who has assessed the patient under the PGD.
Continuing Training & Education	Up to date knowledge in therapeutic area The practitioner must be familiar with the SPC for all medicines supplied in accordance with this PGD. It is the responsibility of the individual to keep up to date with all aspects of practice in this area. Adhere to the GPhC Standards for Pharmacy Professionals May 2017 and subsequent updates.

REFERRAL ARRANGEMENTS & AUDIT TRAIL

Referral arrangements	Ensure patient is aware that if they experience significant symptoms or become systemically unwell following emergency contraception then they should seek medical advice that day either from their GP or through OOH centre.

Records/audit trail	A record of supply should be made on PMR which includes Name, strength, form and pack size of medicine supplies Dose and route of administration Date of supply and name of person making supply The medicine must be labelled in accordance with requirements detailed in the current version of Medicines, Ethics and Practice. The patient's GP must be informed if the patient experiences an adverse drug reaction. A computer or manual record of all individuals receiving a supply under this PGD should also be kept for audit purposes. Records of supply should be kept for 25 years. The approved practitioner must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols.The information relating to the supply of medication of each individual must include as a minimum: • Patient's name and date of birth, • Dose, • Brand, batch number and expiry date of medicine, • Date given and by whom. All records must be clear and legible and, ideally, in an easily retrievable format. The patient's CHI number should be recorded on the CPUS/UCF form where available
Reference sources and comments	1. British National Formulary – Current edition 2. Electronic Medicines Compendium (www.medicines.org.uk) 3. Faculty of Sexual and Reproductive Health Guidance CEU (March 2017, (Amended December 2020) | "Emergency contraception".

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT
Supply of Levonorgestrel 1500 micrograms by Pharmacists for Emergency Hormonal Contraception
Protocol number 323 Version 7

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

I_____ (please print in capitals), confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which the supply of the medicine will take place and agree to provide this medicine only in accordance with this PGD.

I understand that it is the responsibility of the pharmacist to act in accordance with the Code of Ethics for Pharmacists and to keep an up to date record of training and competency. I understand it is also my responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

I have read and fully understand the Patient Group Direction for the administration of Levonorgestrel 1500mcg and agree to provide this medicine only in accordance with this PGD in NHS Forth Valley Community Pharmacies.

Name of Pharmacist (in block capitals)_____

GPhC Number _____ Employee ☐ Locum ☐ Relief Pharmacist ☐

If you are a locum please provide a contact email address: _____

Normal NHS Forth Valley Pharmacy Location
(Please state contractor code)
_____

Signature _____

Date _____

Note :
A copy of this agreement must be signed by each pharmacy practitioner who wishes to be authorised to use the PGD for Administration of Levonorgestrel 1500mcg by Community Pharmacists working in Forth Valley Pharmacies.

Please return this form (page 10) to Community Pharmacy Services, Forth Valley Royal Hospital, Stirling Road, Larbert. FK5 4WR and retain a copy in each pharmacy premises you wish to provide the medicine from. Each authorised pharmacy practitioner should be provided with an individual copy of the authorised PGD and a photocopy of the document showing their authorisation.

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT
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Name of Premises & Contractor Code_____
Address of Premises_____

PROFESSIONAL AGREEMENT

I have read and confirm that I have understood the above named patient group direction. **The people below have been authorised to use this protocol.** I confirm that it is my professional responsibility to ensure all those signed below have had their professional registration confirmed as per normal company processes and have signed the necessary PGD paperwork* to enable them to work within the confines of this PGD.
*The professional signing the PGD paperwork accepts personal responsibility for having undertaken all the mandatory training requirements for the PGD.

Signature of **Lead Pharmacist** for the contractor code

Name (in block capitals)	Signature	Date

Name of Professional (IN BLOCK CAPITALS)	Registration Number	Signature	Date