Patient Group Direction for the Supply of Levonorgestrel 1500mcg tablet (Levonelle® 1500), by Pharmacists, for Emergency Hormonal Contraception

This PGD is adapted from a national template and made specific to NHS Lanarkshire It includes additional and updated information with regard to

- locally available sexual health clinics and referral systems
- local adult and child protection procedures and advice routes
- Copper IUDs being the preferred method of emergency contraception and ulipristal being the preferred formulary medicine
- A 3mg dose being authorised in circumstances where Levonorgestrel is indicated and the patient is >70Kg or > 26Kg/m^2, this dose is also recommended if a patient is taking enzyme inducing medication or has stopped taking this medication in the last 28 days

Pharmacists working within NHS Lanarkshire are required to sign this localised version before providing the service.

An essential element of the PGD involves completion of the assessment and recording form – Appendix 1. The PGD and copies of this Appendix are available from the NHS Lanarkshire section of *www.communitypharmacy.scot.nhs.uk*

UNCONTROLLED WHEN PRINTED

EFFECTIVE FROM July 2018

REVIEW DATE – July 2020

EXTENDED TO NOV 2023 BY

AREA DRUGS AND THERAPEUTICS COMMITTEE TO ALIGN WITH NEW PGD FOR BRIDGING CONTRACEPTION.

1. Authorisation

Adapted for use within NHS Lanarkshire by			
Clinical Lead, Family Planning Services, NHS Lanarkshire	Dr Anne McLellan	Signature	Anne McLellan*
Chair, Primary Care Drugs and Therapeutics Committee, NHS Lanarkshire	George Lindsay	Signature	George Lindsay*

Authorised for use within NHS Lanarkshire

Chief Pharmacist, Primary Care	George Lindsay	Signature	George Lindsay*
Associate Medical Director, Primary Care	Dr Linda Findlay	Signature	Linda Findlay*

* Original Signatures on file with Chief Pharmacist, Primary Care

Date Approved July 2018

Effective from July 2018 Review date 30 July 2020

This policy will be reviewed at least every two years or sooner if current treatment recommendations change

Extended to Nov 2023 by Area Drugs and Therapeutics Committee to align with Bridging Contraception Service

2. Management of the National Patient Group Direction (PGD)

This PGD must be read, agreed to, signed and a copy retained by all pharmacists involved in its use. A copy of the signature sheet should be sent to the NHS Board.

3. Application

This PGD covers the supply of levonorgestrel 1500mcg tablet (Levonelle® 1500) for use as emergency hormonal contraception by female patients who are aged 13 years or over, provided none of the exclusion criteria listed below apply.

It is based upon a national Patient Group Direction for this purpose, supplemented with local child and adult protection information and procedures relevant to NHS Lanarkshire and updated in response to guidance from FSRH.

In addition it provides information on local sexual health clinics available within NHS Lanarkshire.

4. Clinical Situation

Situation	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	NHS Lanarkshire recommendations for Emergency Contraception were revised following the update to the guidance on Emergency Contraception (EC) by the Faculty of Sexual and Reproductive Health in Dec 2017. https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • **All women requiring EC should be offered a Copper containing intrauterine device (Cu-IUD) if appropriate as it is the most effective method of contraception.** Clients can access drop in clinics or seek an emergency appointment. The most up-to-date contacts can be found via http://www.lanarkshiresexualhealth.org/contraception/family-planning/ or by phoning 0300 3030 251. This line is available Mon – Fri 9.00am – 4.45pm • In many cases it is appropriate to provide EC as immediate treatment as well as referring for a Cu-IUD • If a Cu-IUD is not appropriate or acceptable, women should be advised that oral EC should be taken as soon as possible if there has been UnProtected Sexual Intercourse (UPSI) within the last 5 days. • EC providers should advise women that Ulipristal Emergency Contraception (UPA-EC) has been demonstrated to be more effective than Levonorgestrel Emergency Contraception (LNG –EC). UPA-EC is licenced for use up to 120 hours post UPSI. LNG-EC is licensed for up to 72 hours post UPSI. • EC providers should also advise women that the available evidence suggests oral EC administered after ovulation is ineffective. • Breast feeding women should be advised not to breastfeed and to express and discard milk for a week after they have taken UPA-EC. Women who breastfeed should be informed that available evidence indicates that LNG-EC has no adverse effects on breastfeeding or on their infants. • EC providers should be aware that the effectiveness of UPA-EC could theoretically be reduced if a woman has taken progestogen prior to taking UPA-EC • If LNG-EC is indicated in a patient >70kg or >BMI 26kg/m^2 a dose of 3mg is recommended.

	The practical application of this information is illustrated in the decision making algorithms 1 and 2 within the guidelines and the implication is that where oral EC is indicated ulipristal is the medicine of choice for most circumstances. For the community pharmacy EC service the main exceptions where levonorgestrel may still be the preferred choice include: •Patients with severe asthma managed with oral corticosteroids (as ulipristal is contraindicated in this circumstance) •Women requiring EC who are using enzyme inducing drugs should be offered a Cu-IUD if appropriate. A 3mg dose of levonorgestrel can be considered but women should be informed that the effectiveness of this regimen is unknown. (A double dose of ulipristal is not recommended). •Women who have recently taken a progestogen. (e.g missed pill) This PGD is designed to facilitate supply in these circumstances Other inclusion criteria include 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).
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. Patients who are/or may be pregnant. 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 (potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc, lactose monohydrate).

	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 a rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption as Levonelle® 1500 contains 142.5 mg lactose.
Action if Excluded	All excluded patients should be referred to NHS Lanarkshire sexual health services or GP practice. For some patients within CAMGLEN/Northern Corridor the ultimate referral point may be to the Sandyford Clinic in Glasgow. The best source for up-to-date information is www.lanarkshiresexualhealth.org Direct referral process contained within the Unscheduled Care Folder should be used during out of hours period.
Action if Patient Declines	Patient should be advised of the risks of the consequences of not receiving treatment. Record outcome in Patient Medication Record if appropriate and refer to Sexual Health or GP practice. The website www.lanarkshiresexualhealth.org provides an update list of all services. Direct Referral process contained within the Unscheduled Care Folder should be used during out of hours period.
Consent	Prior to the supply of levonorgestrel, consent must be obtained, preferably written, either from the patient, 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.
Consent for under 16s	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.
Additional Local Adult and Child Protection Information and Procedure	All patients regardless of age should be assessed using the proforma (Appendix 1) at the back of this PGD. Regardless of whether patients have a clinical indication for treatment or not, all patients under the age of 16 yrs who present at a pharmacy seeking treatment or advice about sexual health services require to be assessed for potential child protection issues. If any patient aged 12 years or under presents who has had sexual intercourse, there must be an urgent referral to the Child Protection Team. Within conventional working hours North Lanarkshire and South Lanarkshire Council websites provide the best local contact numbers. Outwith conventional working hours the North Lanarkshire contact number is 0800 121 4114 and the South Lanarkshire number is 0800 678 3282. An alternative is to phone 101 Police Scotland and ask for the Family Protection Unit. These numbers should also be used for children 13 years and over and for adults if there is an assessed urgent need. **All** patients under the age of 16 years should also be strongly encouraged to arrange a fast track consultation with a nurse trained and experienced in providing sexual health care to patients under 16. The contact number is 0300 303 0251 . These are manned from 9.00am – 4.45pm Mon – Fri. With the permission of the patient the pharmacist may make the call on the patient's behalf to arrange an appointment. Outwith these opening times of the fast track service the patient can be sign posted to their GP or Out of Hours service as appropriate. The pharmacist should consider making the call on the patient's behalf on the direct professional to professional out of hours contact number available in the unscheduled care PGD folder. The pharmacist may also seek professional advice when assessing a patient from • NHS Lanarkshire sexual health services – Tel 0300 303 0251 • Chief Pharmacist, Primary Care – Tel 01698 858128 As with all services there is an ethos of seeking continual improvement. Thus pharmacists are expected to keep records (Appendix 1) of the patients they see. NHS Lanarkshire will seek feedback from pharmacy contractors on a periodic basis to identify any issues which may benefit from additional education, training or support. Additionally pharmacists are encouraged to be proactive in identifying any such issues to NHS Lanarkshire and this can be done by contacting the Chief Pharmacist for Primary Care on 01698 858128

5. Characteristic of Staff and Premises authorised under the PGD

Staff	A pharmacist whose name is currently on the register held by The General Pharmaceutical Council (GPhC). The pharmacist must be competent to assess a patient's capacity to understand the nature and purpose of the treatment in order to give or refuse consent (Age of Legal Capacity (Scotland) Act 1991). The pharmacist must maintain their own level of competence and knowledge in this area to provide the service.
Premises	Premises should provide an acceptable level of privacy to respect patient's right to confidentiality and safety.

6. Description of Treatment

Name of Medicine	Levonorgestrel (Levonelle® 1500)
Legal Status	Prescription only medicine (PoM)
Dosage Form/Strength	Tablet 1500 microgram (mcg)
Storage	Store in original container below 25°C
Dose	Female patients of 13 years and over – Take 1500mcg 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 using an enzyme-inducing medication or has stopped taking such medication within the last 28 days (see interacting medications), then TWO tablets of levonorgestrel 1500mcg should be taken as the single dose (total dose 3000mcg 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. Patients taking enzyme inhibiting medication may experience adverse effects and may require additional monitoring (see interacting medications). If LNG-EC is indicated in a patient >70kg or >BMI 26kg/m^2 a dose of 3mg is recommended. If vomiting occurs within 3 hours of taking the original dose, another dose should be taken immediately.
Total Dose	1500mcg (one tablet) as a single dose, or 3000mcg (two tablets)[2] as a single dose (if patient also taking enzyme-inducing medication or has stopped taking such within last 28 days or is >70Kg or > 26Kg/m^2)
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.
Advice to Patient (verbal)	Advise the patient in accordance with the advice provided in Appendix 1 to this PGD. If the patient is taking the oral contraceptive pill or using the contraceptive patch and emergency hormonal contraception is required, advise the patient to use a barrier method <u>in addition</u> to her usual method until she has taken the pill or applied the patch correctly for 7 consecutive days. (If taking Qlaira® - 9 days) If the patient is not using an oral contraceptive pill, a barrier method of contraception should be used until appropriate contraceptive advice from Sexual Health Service or GP is given.

Patient Information (written)	1. Patient Information Leaflet provided with medication. (Levonelle® 1500). 2. Written information about locally available contraception services and methods of contraception. 3. Written information about locally available services providing sexual health advice.
Documentation	The pharmacist must ensure maintenance of records for each supply (Appendix 1) and may be required to share information with appropriate parties in line with confidentiality protocols.
Follow-up	None required.
Side Effects	Menstrual irregularities, nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting.
Drug Interactions	***Reduced efficacy of Levonorgestrel (Levonelle® 1500)*** The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers, and these medications can reduce the efficacy of levonorgestrel. A full list is available in 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, Topiramate. Anti-Fungal: Griseofulvin Herbal Medicines containing Hypericum perforatum (St. John's wort). Rifamycins: Rifampicin, Rifabutin Endothelin receptor antagonist: Bosentan ***Effect of Levonorgestrel (Levonelle® 1500) on other medication*** Immunosuppressants: metabolism of ciclosporin reduced (increased plasma concentration) Caution is advised when prescribing for patients using the anticoagulant drugs, phenindione and warfarin. Anticoagulant effects may be altered following use. Patients should be advised about potential drug interactions and attention should be paid to their anticoagulation monitoring. Requirements of oral anti-diabetics and insulin can change as a result of taking levonorgestrel (Levonelle® 1500), therefore the patient with diabetes should be advised to monitor blood glucose levels closely
Patient Charges	None. Current NHS exemption is applicable.
Record/Audit Trail	There must be appropriate records kept (See example proforma Appendix 1) and maintained by the pharmacist to enable verification of service provision and training requirements, and to provide information for internal and external audit and for evaluation purposes.

PATIENT GROUP DIRECTION FOR SUPPLY OF LEVONORGESTREL 1500MCG TABLET (LEVONELLE® 1500), BY PHARMACISTS, FOR EMERGENCY HORMONAL CONTRACEPTION

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. It is also your responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

Note to Authorising Authority: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to provide the levonorgestrel 1500mcg tablet (Levonelle® 1500) only in accordance with this PGD.

Name of Pharmacist			
GPhC Registration Number			
Normal Pharmacy Location Address including Contractor Code			
Signature		Date	

Signed copy to be returned to

Pharmacy Administration Team
Secretary to Chief Pharmacist, Primary Care,
NHS Lanarkshire Headquarters
Kirklands
Fallside Road,
Bothwell,
G71 8BB
e-mail Pharmacy.adminteam@lanarkshire.scot.nhs.uk

EMERGENCY HORMONAL CONTRACEPTION AIDE MEMOIR – LEVONORGESTREL AND ULIPRISTAL ACETATE

This proforma is designed to aid decision making for community pharmacists providing the emergency contraception public health service in NHS Lanarkshire. It is intended to be used flexibly by community pharmacists as an aide-memoir about key points to discuss during a consultation.

It is important to be aware of the key advice for emergency contraception within NHS Lanarkshire before using the proforma. This is shown below and was developed following the update to the guidance on Emergency Contraception (EC) by the Faculty of Sexual and Reproductive Health in December 2017.
https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/

- **All women requiring EC should be offered a Copper containing intrauterine device (Cu-IUD) if appropriate as it is the most effective method of contraception.** Clients can access drop in clinics or seek an emergency appointment. The most up-to-date contacts can be found via http://www.lanarkshiresexualhealth.org/contraception/family-planning/ or by phoning 0300 3030 251. This line is available Mon – Fri 9.00am – 4.45pm
- In many cases it is appropriate to provide EC as immediate treatment as well as referring for a Cu-IUD
- If a Cu-IUD is not appropriate or acceptable, women should be advised that oral EC should be taken as soon as possible if there has been UnProtected Sexual Intercourse (UPSI) within the last 5 days.
- EC providers should advise women that Ulipristal Emergency Contraception (UPA-EC) has been demonstrated to be more effective than Levonorgestrel Emergency Contraception (LNG –EC). UPA-EC is licenced for use up to 120 hours post UPSI. LNG-EC is licenced for upto 72 hours post UPSI.
- EC providers should also advise women that the available evidence suggests oral EC administered after ovulation is ineffective.
- Breast feeding women should be advised not to breastfeed and to express and discard milk for a week after they have taken UPA-EC. Women who breastfeed should be informed that available evidence indicates that LNG-EC has no adverse effects on breastfeeding or on their infants.
- EC providers should be aware that the effectiveness of UPA-EC could theoretically be reduced if a woman has taken progestogen prior to taking UPA-EC (e.g. missed pill).
- If LNG-EC is indicated in a patient >70kg or >BMI 26kg/m^2 a dose of 3mg is recommended.

The practical application of this information is illustrated in the decision making algorithms 1 and 2 within the guidelines and the implication is that where oral EC is indicated ulipristal is the medicine of choice for most circumstances. For the community pharmacy EC service the main exceptions where levonorgestrel may still be the preferred choice include:

- Patients with severe asthma managed with oral corticosteroids (as ulipristal is contraindicated in this circumstance)
- Women requiring EC who are using enzyme inducing drugs should be offered a Cu-IUD if appropriate. A 3mg dose of levonorgestrel can be considered but women should be informed that the effectiveness of this regimen is unknown. (A double dose of ulipristal is not recommended).
- Women who have recently taken a progestogen. (e.g. missed pill).

Ulipristal is a “Pharmacy Only” and supply does not require a Patient Group Direction PGD.
A PGD is available to enable the “POM” version of levonorgestrel to be supplied where it is indicated.

DATE:		**CLIENT NAME:**			
CHI:		**AGE:**	***WEIGHT***	**HEIGHT**	**BMI**

If 13, 14,15 YEARS OLD		
EXPLAIN CONFIDENTIALITY AND LIMITS		
Who is with her?	Who knows where she is?	
Hold old is partner?	Lives with family / friends / in care / homeless	
Attends school Y / N	Concerns drugs / alcohol? Y / N	
Concerns re assault / abuse? Y / N	Is there social care involvement? Y/N	
COMPETENT TO CONSENT	*Yes*	
	Not competent / under 13 yrs old / child protection issues	
NB If there is a Child or Adult Protection concern a referral should be made via North Lanarkshire 0800 121 4114 or South Lanarkshire 0800 678 3282 or via the Police Scotland Family Protection Unit on 101.		
All under 20s should be encouraged to attend Sexual Health Services http://www.lanarkshiresexualhealth.org/contraception/family-planning or telephone 0300 3030 251 for the purposes of pregnancy testing, risk assessment, future contraception and STI screening. An APP for young people aged 20 and under which provides information about contraception, STI testing and treatment, BBV testing, free condoms, general information and advice can also be recommended. The APP is called "YP Services" and is available to download from the App Store through Apple or Google Play for free.		

Last Menstrual Period:	*NORMAL?*	*Y/N*		*CYCLE*	*(DAYS)*	*REGULAR?*	*Y/N*	
PREGNANCY TEST	*NOT DONE*			*NEGATIVE*		*POSITIVE*		
(Consider test if period late or LMP unsure or LMP unusual)								
CIRCUMSTANCES	UPSI		CONTRACEPTIVE FAILURE		OTHER:			
CURRENT CONTRACEPTION								

WHEN WAS THE FIRST UPSI SINCE THE START OF THE PATIENT'S LAST PERIOD OR SINCE HORMONAL METHOD FAILURE?

DATE		TIME	
HOURS SINCE First UPSI TO CURRENT CONSULTATION			
DAY IN CYCLE OF First UPSI			
All women requiring EC should be offered a Copper containing intrauterine device (Cu-IUD) if appropriate as it is the most effective method of contraception. In many cases it is appropriate to provide EC as immediate treatment as well as referring for an IUD			

IMPORTANT FACTORS IN DECISION MAKING			
	No	YES	
ANY EC ALREADY THIS CYCLE?			If EC used this cycle and a repeat is indicated it is important to use the same oral medicine. If in any doubt refer for a coil or expert advice
SEXUAL ASSAULT?			Provide immediate treatment and refer to sexual health services
KNOWN ALLERGY TO ULIPRISTAL			If YES consider IUD, referral or levonorgestrel.
KNOWN ALLERGY TO LEVONORGESTEL			If YES consider IUD, referral or ulipristal
FOR ULIPRISTAL - SEVERE ASTHMA TREATED BY ORAL GLUCOCORTICOIDS			If YES consider IUD, referral or levonorgestrel
ENZYME INDUCING MEDICATION* WITHIN PAST 28 DAYS			If YES refer for IUD or double dose levonorgestrel as authorised by PGD
RECENT USE OF PROGESTOGEN			If YES consider IUD, referral or levonorgestrel
CURRENTLY BREASTFEEDING			Be aware of implications for ulipristal. Consider LNG
If LNG-EC IS INDICATED IN A PATIENT >70kg OR >BMI 26kg/m^2			A dose of 3mg LNG is indicated as authorised by PGD
HEPATIC DYSFUNCTION, PORPHYRIA, SEVERE MALABSORPTION SYNDROME OR UNEXPLAINED VAGINAL BLEEDING.			If YES Refer to Sexual Health Services
ON INTERACTING MEDICATION*****			Refer current BNF or SPC for details
CONSIDER BRIDGING CONTRACEPTION			

PLANNED TREATMENT		
IUD Advised		Details:
IUD advised and UPA-EC provided.		
IUD advised and LNG-EC 1500mg provided.		
IUD advised and LNG-EC 3mg provided. 3mgfor patients receiving enzyme inducing medicines or BMI >26kg/m^2 or weight >70kg.		
Bridging Contraception advised		
No EC indicated		
Referred for specialist services		

ADVICE CHECKLIST	
How to take tablets	
Action if vomits within 3 hours	
Next period may be early/late	
May be light bleeding next few days, don't count as period	
Pregnancy test in 3 weeks advised unless normal period	
If oral EHC fails not known to be harmful to pregnancy	
Return if further UPSI	
Provide information on access to regular contraception (and APP for under 20 year olds)	
Breast feeding women should be advised not to breastfeed and to express and discard milk for a week after they have taken ulipristal	
Women who breastfeed should be informed that available limited evidence indicates that Levonorgestrel has no adverse effects on breastfeeding or on their infant.	
STI risk discussed and options for testing provided	

EC SUPPLY

Name of drug:	Strength	Batch Number:	Expiry

Pharmacist (Print name & sign) _____Date:

TO BE RETAINED FOR 7 YEARS