PATIENT GROUP DIRECTION

FOR THE ADMINISTRATION OF LEVONORGESTREL 1500 micrograms TABLET
BY COMMUNITY PHARMACISTS FOR
EMERGENCY HORMONAL CONTRACEPTION

THE COMMUNITY PHARMACIST SEEKING TO ADMINSTER LEVONORGESTREL 1500 micrograms TABLET MUST ENSURE THAT ALL PATIENTS HAVE BEEN SCREENED AND MEET THE CRITERIA BEFORE ADMINISTRATION TAKES PLACE

NHS Highland has authorised this patient group direction to help patients by providing them with more convenient access to an efficient and clearly defined service within NHS Highland. It cannot be used until Appendices 1 & 2 are completed.

Warning- Document uncontrolled when printed

Further information on the use of Patient Group Directions in NHS Highland and the PGD procedure can be obtained from
http://intranet.nhsh.scot.nhs.uk/Organisation/ADTC/PGDSG

PATIENT GROUP DIRECTION FOR THE ADMINISTRATION

OF LEVONORGESTREL 1500 micrograms TABLET

Management and monitoring of patient group direction

Prepared by:	
Medical Practitioner	Name: Dr Hame Lata Title: Consultant, Sexual & Reproductive Health Signature ……
Senior representative of the professional group who will provide care under the direction.	Name: Jackie Agnew Title: Area Regulations, Contracts & Controlled Drugs Governance Pharmacist Contact details: Telephone: 01463 706830 Fax: 01463 713844 Signature ……
Pharmacist	Name: Findlay Hickey Title: Lead Pharmacist (West) North & West Operational Unit Signature ……
Authorised by:	
Patient Group Direction Sub-group Chair or Secretary	Name: Mark Smith Title: Chair Signature……..
Date of ratification of the direction on behalf of the Area Drug & Therapeutics Committee	Date:
Review Date	Two years from final ratification and every two years thereafter. Or when there is a change in clinical practice, evidence or the Summary of Product Characteristics for any of the medicines included is updated, whichever is first.

Clinical indication to which this patient group direction applies

Definition of situation/condition	Female patient presenting in person at the community pharmacy requesting emergency hormonal contraception (EHC) for their own use within 72 hours of unprotected sexual intercourse (UPSI) and wishing to avoid the possibility of a resulting unintended pregnancy. Trial data have shown that the pregnancy rate is lower following treatment with ulipristal (ellaOne®) than with levonorgestrel. Levonorgestrel should therefore be reserved for when ulipristal is not an option.
Clinical criteria for inclusion	Patient is aged 13 years or over. Patient gives her consent to providing the relevant clinical information to the pharmacist after the pharmacist has assessed her capacity to consent. *(Refer to "*Consent" *on pages 9-10.)* **Unprotected sexual intercourse/contraception failure within the last 72 hours:** <u>Unprotected Sex</u> Can arise from a number of circumstances, for example, sexual intercourse where no contraceptive method used, ejaculation on external genitalia, coitus interruptus/failed coitus interruptus, rape or sexual assault. <u>Potential barrier method failures</u> Condom rupture, dislodgement or misuse. Diaphragm/cap inserted incorrectly, torn, dislodged during intercourse or removed before recommended time. <u>Potential combined pill failure when alternative methods not used or failed</u> For combined pills, efficacy is compromised if two or more pills are missed from the first seven in the pack and unprotected sexual intercourse took place in either pill free week or week 1 of pack. If pills are missed from week 3, patient should be advised to complete this pack and commence a new pack the next day therefore having no pill-free interval. If the pill-free interval is avoided in this way she does not require emergency hormonal contraception. <u>Potential progesterone-only pill failure when alternative methods not used or failed</u> For progesterone only pills, contraceptive efficacy is compromised if one or more pills are missed or taken more than three hours late, with the exception of desogestrel 75 micrograms tablets e.g. Cerazette®, Aizea®, Cerelle® & Nacrez®, which can be taken within 12 hours of normal pill time. <u>Intra-uterine devices (IUDs) / intra-uterine system (IUSs)</u> Removal of IUDs/IUSs within 7 days of sexual intercourse.

Clinical criteria for exclusion	• 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 does not agree to share relevant clinical information or there is no valid consent. • Patient who the pharmacist has assessed as not being competent to consent. (*Refer to "*Consent" *on Pages 9-10.)* • More than 72 hours from episode of unprotected sex. • Unexplained vaginal bleeding.. • Pregnancy. • Patient has given birth within last 3 weeks. • Previous use of EHC in current menstrual cycle. • Delay of menstruation by more than 5 days or any other reason to suspect pregnancy • Known hypersensitivity to levonorgestrel and other progestogens or tablet excipients within these tablets (e.g. potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc, lactose monohydrate). • Patients with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption as tablet contains lactose monohydrate. • Current use of ciclosporin • Porphyria. • Severe hepatic dysfunction. • Severe malabsorption syndromes e.g. Crohn's Disease, ulcerative colitis, severe diarrhoea.
Criteria for seeking further clarification from doctor	Patients who fall into the categories detailed in the exclusion criteria. Pharmacists should not administer if they feel that it is inappropriate for the patient.
Action if patient excluded from treatment	Refer patient to Sexual Health Service or GP practice. During out-of-hours the direct referral process detailed in the Unscheduled Care folder should be used. The reason why the patient was excluded under the PGD will be documented in the Patient Medication Record (PMR). If unprotected sex was within the last 5 days (120 hours) the patient may still be suitable for a copper-intrauterine device (copper-IUD) insertion or use of an ulipristal (EllaOne®) tablet. Assessment or referral should be made in a suitable timeframe to allow this to happen.
Action if patient declines treatment	Patient should be advised of the risks and the consequences of not receiving treatment. Record the outcome in the PMR and refer the patient to Sexual Health Service or GP practice. During out-of-hours the direct referral process detailed in the Unscheduled Care folder should be used.

Characteristics of staff authorised to take responsibility for the supply or administration of medicines under the patient group direction

Qualifications required	A person whose name is currently maintained on the register of pharmacists held by the General Pharmaceutical Council (GPhC). Pharmacists must maintain their own level of competence and knowledge in this area to provide the service.
Initial training	Received and understood training to undertake the supply of medicines under a PGD and must be familiar with the content of the NHS Highland PGD PowerPoint presentation. Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD. Has an understanding of child protection and vulnerable adult issues and has undertaken training as per local requirements.
Competency assessment	The pharmacist should be competent to assess the person's capacity to understand the nature and purpose of the treatment in order to give or refuse consent.
Ongoing training and competency	The pharmacist must be familiar with the Summary of Product Characteristics (SPC) for levonorgestrel administered 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.

Description of treatment available under the patient group direction

Name, form & strength of medicine	Levonorgestrel 1500 micrograms tablet
Legal status	Prescription Only Medication (POM)
Indicate any off-label use (if relevant)	Current use, or within last 4 weeks, of liver enzyme modifying drugs. For example, medicines used to treat epilepsy (e.g. barbiturates, primidone, phenytoin, carbamazepine), tuberculosis (e.g. rifampicin, rifabutin), HIV (e.g. ritonavir, efavirenz), fungal infections (e.g. griseofulvin). Herbal remedies that contain St John's wort (Hypericum perforatum) also reduce levonorgestrel levels. In this situation, TWO tablets of levonorgestrel 1500 micrograms should be taken as a single dose. This is an unlicensed indication and is not included in the Summary of Product Characteristics (SPC), but is a recommendation of the Faculty of Sexual and Reproductive Healthcare Clinical Guideline on Emergency Contraception. Further guidance on efficacy and recommended treatment for this patient group can be found at www.fsrh.org.uk and in Drug Safety Update.
Route/Method of Administration	Oral
Frequency of dose/ duration of treatment	One tablet (or two tablets if taking enzyme-inducing medication) of 1500 micrograms to be taken as a single dose as soon as possible after unprotected intercourse, but no later than 72 hours after.
Quantity to be administered and/or supplied	One tablet (or two tablets if taking enzyme-inducing medication)
Maximum or minimum treatment period	Can be repeated if vomiting occurs within three hours of treatment

Advice to be given to patient	**The option of a copper-IUD should be discussed with ALL patients requesting emergency contraception even if presenting within 72 hours. Efficacy of the IUD is superior to that of levonorgestrel, the failure rate is estimated at no greater than 1% and allows ongoing contraceptive benefit. The IUD can be inserted up to 5 days after unprotected sexual intercourse or if time of ovulation can be reliably estimated up to 5 days following ovulation (i.e. up to day 19 of menstrual cycle in regular 28 day cycle).** Advise women using liver enzyme-inducing drugs that a copper-IUD is the preferred option. **Efficacy:**

If 100 women have one episode of unprotected sex	**Days 9 to 18 of cycle**	**Days 1 to 8 or 19 to 28**
Number of pregnancies if no EC is used	20 to 30 pregnancies	2 to 3 pregnancies
Levonorgestrel within 72 hours of unprotected sex	3 to 4 pregnancies	<1 pregnancy

Discuss the mode of action, failure rate and possible effects on the foetus of levonorgestrel - See relevant SPC. There are no clinical data on effect on foetus by levonorgestrel but it should be avoided. If pregnancy is a possibility this should be excluded before supply is made.

For patients who have missed their oral contraceptive pill, give advice based on the EHC e-learning module developed by NES Pharmacy which can be found at https://www.portal.scot.nhs.uk or the Faculty of Sexual and Reproductive Health Statement on missed pills https://www.fsrh.org/documents/cec-ceu-statement-missed-pills-may-2011/

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 in addition 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.

Highlight that the patient's next period may be early or late.

Advise the patient that levonorgestrel may cause nausea and/or vomiting. If vomiting, or serious diarrhoea, occurs within three hours of taking the medication further advice should be sought immediately from the pharmacist, or other appropriate agency.

Advise the patient that levonorgestrel is an occasional method of contraception and must not be used as a replacement for a regular contraceptive method. Provide local information about how to access a local contraception service and contraceptive advice.

Advise the patient that she should consider being tested for a sexually

	transmitted infection and provide local information about where she can obtain that service. If the patient has not had her period within 5 days of their expected date of menstruation, abnormal bleeding occurs or pregnancy is suspected, she should be advised to attend the Sexual Health Service, GP or pharmacy (if pregnancy testing is provided) with a urine sample to confirm or exclude pregnancy. If patient is breast-feeding, advise levonorgestrel is not thought to be harmful but potential exposure of her baby can be reduced if she takes the dose immediately after feeding her baby. Requirements of oral anti-diabetics and insulin can change as a result of taking levonorgestrel therefore any patient with diabetes should be advised to monitor blood glucose levels closely.
Follow up treatment	Patient advised to have a pregnancy test if amenorrhoea persists for 3 weeks after taking levonorgestrel. Ensure that patient understands how to get repeat dose if required. Can be used more than once in the cycle, if clinically indicated.
Written information to be given to the patient	1. Patient Information Leaflet provided with medication. 2. Patient information leaflets on emergency & routine contraception. 3. NHS Health Scotland leaflet “What do you know about Chlamydia”. 4. Written information about locally available services providing sexual health advice and their opening times.
Identifying and managing possible adverse reactions	If an adverse reaction does occur give immediate treatment and inform a relevant medical practitioner as soon as possible. Report the reaction to the MHRA using the Yellow Card System, **https://yellowcard.mhra.gov.uk/**.
Referral for medical advice	Appearance or suspicion of an adverse reaction, as above.
Facilities and supplies required	Confidential environment. CPUS prescription forms. Supply of levonorgestrel tablets. Drinking water and cup. Patient information leaflets.
Consent	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.**
Details of records required	The pharmacist must complete and retain the Emergency Hormonal Contraception Proforma (Appendix 3) to enable verification of service provision and training requirements, and to provide information for internal and external audit and for evaluation purposes. The minimum NHS retention periods for these forms are as follows: • For those over 16 years old – retain for 6 years • For those under 16 years old – retain until the patient's 25th birthday A CPUS prescription form should be completed and submitted to PSD for any supplies of levonorgestrel made. The supply should be recorded in the Patient Medication Record (PMR).
References	BNF No. 71, available at: www.medicinescomplete.com, accessed on 13/7/2016 SPC Available at: www.medicines.org.uk/emc, accessed on 13/7/2016 *Faculty of Sexual & Reproductive Healthcare Clinical Guidance Emergency Contraception August 2011 (Updated January 2012)*. Available at: https://www.fsrh.org/documents/ceu-emergency-contraception-jan-2012/, accessed on 13/7/2016 NES – *Sexual & Reproductive Health* and *Contraception January 2015* eLearning modules. Available at: https://www.portal.scot.nhs.uk/, accessed on 13/7/2016

Appendix 1

Health professionals approved to provide care under the direction.

To be retained in the community pharmacy as a record of those pharmacists who have signed the PGD.

An Individual Authorisation form (Appendix 2) should be completed and returned to the Pharmacy Services Office

The **lead professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The **manager** who approves a healthcare professional to supply and/or administer medicines under the patient group direction, is responsible for ensuring that he or she is competent, qualified and trained to do so and for maintaining an up-to-date record of such approved persons in conjunction with the Head of Profession.
The **healthcare professional** who is approved to supply and/or administer medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration or supply is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.
PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF LEVONORGESTREL 1500 micrograms TABLET BY COMMUNITY PHARMACISTS FOR EMERGENCY HORMONAL CONTRACEPTION IN NHS HIGHLAND
Local clinical area(s) where these healthcare professionals will operate this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Appendix 2

PATIENT GROUP DIRECTION

FOR THE ADMINISTRATION OF LEVONORGESTREL 1500 micrograms TABLET

BY COMMUNITY PHARMACISTS FOR

EMERGENCY HORMONAL CONTRACEPTION IN NHS HIGHLAND

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

The **healthcare professional** who is approved to supply medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that the supply is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.

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 levonorgestrel 150 micrograms tablet in accordance with this PGD.

Name of Pharmacist _____

GPhC Registration Number _____

Normal Pharmacy Location (if pharmacy locum please provide contact details) _____

Signature _____ Date _____

Signed copy to be returned to

Admin Assistant
Community Pharmacy Services
Assynt House
Beechwood Park
Inverness
IV2 3BW

FAX: 01463 713844

NHS Highland

Appendix 3 **EMERGENCY HORMONAL CONTRACEPTION PROFORMA**

Pharmacy Stamp

DATE _____ **CLIENT NAME** _____

CHI _____ **AGE** _____

If 13, 14, 15 YEARS OLD

EXPLAIN CONFIDENTIALITY AND LIMITS ☐

Who is with her? _____ Who knows she is here?

How 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

COMPETENT TO CONSENT Yes ☐

Not competent/ under 13 yrs old/ child protection issues ☐ Inform Police

Last Menstrual Period (LMP): NORMAL? Y / N CYCLE (Days) _ REGULAR? Y / N

PREGNANCY TEST NOT DONE ☐ NEGATIVE ☐ POSITIVE ☐

(Do test if period late or LMP unsure or LMP unusual)

CIRCUMSTANCES: **UPSI** ☐ CONTRACEPTIVE FAILURE ☐ OTHER: _____

WHEN WAS THE FIRST UPSI SINCE THE START OF HER LAST PERIOD OR SINCE HORMONAL METHOD FAILURE?

DATE _____ TIME

HOURS SINCE _____ > 72 hours since 1st UPSI - Refer

DAY IN CYCLE OF 1st UPSI _____

	NO	YES	
ANY EHC ALREADY THIS CYCLE?	☐	☐	If already used EHC this cycle - Refer
SEXUAL ASSAULT?	☐	☐	If assault refer to local guidelines
PREVIOUS VOMIT WITH EHC?	☐	☐	

MEDICAL HISTORY:

	NO	YES	
KNOWN ALLERGY TO LEVONORGESTREL TAB	☐	☐	If YES Refer
SEVERE HEPATIC DYSFUNCTION	☐	☐	If YES Refer
SEVERE ABSORPTION DIFFICULTIES	☐	☐	If YES Refer
PORPHYRIA	☐	☐	If YES Refer

COMPARATIVE ESTIMATED EFFICACY OF EMERGENCY CONTRACEPTIVE (EC) METHODS

If 100 women have one episode of unprotected sex	Days 9-18 of cycle	Days 1 to 8 or 19 to28 of cycle
Number of pregnancies if no EC used	20 to 30 pregnancies	2 to 3 pregnancies
Cu-IUD before implantation i.e. until day 19 or <120 hrs any time of cycle	< 1 pregnancy	< 1 pregnancy
Levonorgestrel within 72 hrs of unprotected sex	3 to 4 pregnancies	< 1 pregnancy
Levonorgestrel between 72 & 120 hrs (unlicensed) – **REFER**	9 pregnancies	1 pregnancy
Ulipristal within 120 hours - **REFER**	< 3 to 4 pregnancies	< 1 pregnancy

SEVERE MALABSORPTION SYNDROME ☐ ☐ If YES Refer
UNEXPLAINED VAGINAL BLEEDING ☐ ☐ If YES Refer
ON INTERACTING MEDICATION ☐ ☐ If YES Consider referral
ENZYME INDUCING MEDICATION ☐ ☐ If YES, refer for IUD or double dose EHC
(Refer to current BNF)

BOTH ORAL AND IUD EMERGENCY CONTRACEPTION DISCUSSED ☐

PLANNED TREATMENT

LEVONORGESTREL 1500 micrograms as single dose (PGD supply) ☐

LEVONORGESTREL 3000 micrograms as single dose (enzyme inducers) (PGD supply – off licence) ☐

Referred for IUD / Ulipristal: ☐
Referred for STI testing ☐
Referred for Contraceptive Advice: ☐

Too late for tablets but declines IUD or ulipristal ☐

Too late for any EHC ☐

No EHC needed at all ☐

Details_____

CURRENT CONTRACEPTION

Patch ☐ COC ☐ POP ☐ injection ☐ implant ☐ IUD/S ☐

Other ☐ _____

Continue pills / patch + condoms too for 7 days ☐
Start pills / patch first day of next period ☐

ADVICE CHECKLIST

How to take tablets ☐
Action if vomits within 3 hours ☐
Next period may be early/late ☐
Return if further UPSI ☐

Failure rate ☐
Pregnancy test in 3 weeks unless normal period ☐
If Levonorgestrel EHC fails not harmful to pregnancy ☐
Written information on access to regular contraception ☐

May be light bleeding next few days, don't count as period ☐

STI risk discussed ☐

SEXUALLY TRANSMITTED INFECTION

14 day window period for Chlamydia, Gonnococcal & Trichomoniasis swabs ☐

3 month window period for Syphilis, Hepatitis B, C, HIV ☐

Provide written information on STI testing services ☐

LEVONORGESTREL SUPPLY

BATCH NUMBER _____ EXPIRY _____

SIGNATURE OF PHARMACIST _____

DATE

PRINT NAME _____