PATIENT GROUP DIRECTION (PGD)
Levonorgestrel (LNG-EC) 1500 microgram tablet

Version:	Final (version 5)
Name of Originator/Author:	Philip Wells – Operational Service Manager- Pubic Health Nursing
Approved by:	Trudi Grant, Director of Public Health Somerset County Council
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SOMERSET PATIENT GROUP DIRECTION (PGD)
FOR THE SUPPLY OF LEVONORGESTREL

VERSION CONTROL

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Version	**Date**	**Comments**
1	01/02/2019	Philip Wells
2	27/03/2019	Dr Andrew Tressider
3	03/04/2019	Rebecca Myers
4	04/04/2019	Michelle Hawkes
5	05/04/2019	Cheryl Vidall

Author	Philip Wells – Operational Service Manager- Pubic Health Nursing
Document reference	

PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF LEVONORGESTREL

Drug: Levonorgestrel (LNG-EC) 1500 microgram **Condition: Emergency Hormonal Contraception** **Professional Group: Registered Nurses**

You must be Authorised by Name, Under the Current Version of this PGD before you attempt to work according to it

Clinical Condition		
1.	**Define condition / indication**	Females aged 12 years and older requiring emergency hormonal contraception (EHC) within 72 hours of unprotected sexual intercourse (UPSI) or failed contraception. In exceptional circumstances between 72 hours and 96 hours of UPSI (although efficacy decreases with time).
2.	**Inclusion criteria**	Females aged 12 years and over where: • No contraceptive method was used, *or* • A contraceptive method is suspected or known to have failed, *or* • A 'pill error' has occurred where emergency contraception is indicated (Refer to Faculty of Sexual & Reproductive Healthcare (FSRH) guidance) • Vomiting has occurred within 3 hours (FSRH guidance) of a dose of levonorgestrel 1500 microgram (see section on relevant warnings below) **And** *all* the following criteria are met: • The individual has had UPSI within the previous 72 hours, or in exceptional circumstances between 72 hours and 96 hours after UPSI; Progestogen-only emergency contraception (POEC) is the most appropriate treatment. All methods of emergency contraception (EC) have been discussed; considerations include if UPSI likely to have taken place during 5 days prior to estimated day of ovulation, more than 96 hours since UPSI and immediate quick-start of regular contraception important • A discussion has occurred with the individual regarding alternative emergency contraception methods - Ulipristal and copper intrauterine device (IUD) - to allow the individual to make an informed choice, and a referral is offered. This should include that insertion of an IUD is the most effective form of emergency contraception, can be fitted for free up to 120 hours after UPSI, and provides the additional benefit of on-going contraception. If the patient chooses an IUD, provided the individual has presented within 72 hours of UPSI and there are no other contraindications, levonorgestrel can still be offered as a precaution (in case the patient misses the appointment)

		• The individual has taken POEC on NO MORE than ONE occasion in the current menstrual cycle • If postpartum, 21 days or more have elapsed since giving birth • Valid consent from patient or person with parental responsibility has been obtained If under the age of 16 years, meeting the criteria of the 'Fraser ruling' regarding consent to treatment ('Fraser competence'). Discussion with the young person should explore the following issues: • Whether the individual is sufficiently mature to understand the advice given; • Advice and encouragement to discuss the situation with parents/guardian; • The effect on physical/mental health if advice/treatment is withheld; • Whether supply of EHC is in the best interest of the individual;
3.	**Exclusion criteria**	For individuals **under the age of 16 years**: • Not meeting the criteria of the 'Fraser ruling' regarding consent to treatment ('Fraser competence') if consent to treatment has not been obtained from a person with parental responsibility for the individual • Issues of child-protection have not been considered • Children aged 12 where a healthcare professional with expertise in child protection issues has not been consulted prior to supply under this PGD For individuals **under 12**: • Supply is not available under this PGD. A child protection expert must be contacted, and the patient must be managed according to child protection protocol **Other exclusion criteria**: • Between 72 and 120 hours has elapsed since UPSI and access to another service for **ellaOne®** (Ulipristal) 30mg or IUD more appropriate • More than 120 hours has elapsed since UPSI • Unprotected sexual intercourse within 12-hours of a previous dose of POEC • **Vomiting more than 3 hours after** ingesting Levonorgestrel - If the individual has received Levonorgestrel but has vomited *more* than 3 hours after the dose was taken then they do not need to take a repeat dose • **Less than five days following ingestion of Ulipristal emergency contraception**

		• Two previous administrations of emergency hormonal contraception (EHC) within the current menstrual cycle • Known, or suspected, pregnancy – including UPSI more than 120 hours earlier within the same menstrual cycle • Patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy) • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption should not take this medicine • Significant abnormal vaginal bleeding of unknown cause - refer to a doctor • Postpartum less than 21 days (contraception not required until ≥ 21 days) • Severe liver disease / hepatic dysfunction • Porphyria • Individuals suffering from bowel disease / disorders (e.g. Crohn's disease, Ulcerative colitis etc) causing malabsorption • Individuals taking ciclosporin – increased risk of toxicity of ciclosporin • The individual requesting EHC is not present in a face to face consultation (i.e. supply under this PGD is not allowed through telephone consultations etc.) • Allergy / hypersensitivity to any component of the levonorgestrel tablets to be supplied (maize starch, talc, magnesium) or any other progestogen If patient has already taken UPA-EC, LNG-EC should not be taken in the following 5 days. **Cautions (including any relevant action taken)** • If >96hours post-UPSI LNG-EC may not be effective: only supply if LNG-EC is the most appropriate form of emergency contraception • Lactose intolerance reported – LNG-EC contains lactose: clarify severity of lactose-intolerance and provenance of diagnosis. Oral EC may not be appropriate; IUD may be the only intervention option available
5.	**Action if excluded**	• Refer to medical practitioner or non-medical prescriber as appropriate • Document refusal or exclusion in patient's records
6.	**Action if patient declines or is excluded**	• Refer to medical practitioner or non-medical prescriber as appropriate • Document refusal or exclusion in patient's records
7.	**When further Medical**	If Body mass index (BMI) greater than 26kg/m2 or weight greater than 70kg the dose of LNG-EC should be doubled (3mg) (FSRH guidance)

	Advice / Advice should be sought	If UPSI is likely to have taken place 5 days prior to estimated day of ovulation consider if UPA-EC is more appropriate • **Other medications** - Consult current BNF for any potential interactions • **Known hypersensitivities** to any component of the levonorgestrel tablets, or any other progestogen, or having shown hypersensitivity after previous administration • **Suspected pregnancy** – levonorgestrel can still be given as there is no evidence that it is harmful, but the patient should be advised to do a pregnancy test to exclude pregnancy Anticoagulants – the anticoagulant effect of warfarin and phenindione is enhanced: the patient should be referred to GP to ensure follow-up and INR is checked three-days after POEC If the patient is taking / has taken rifampicin or rifabutin then metabolism of levonorgestrel may be enhanced for four weeks after treatment stops, even if only a short course (e.g. two days) was given. A different emergency contraceptive method may be advised. Children under 13 years of age - a healthcare professional with extensive expertise in child protection **MUST** be consulted before supply can be considered. Supply may ONLY be made to children under the age of 13 if healthcare professional consulted is in agreement that supply may be made. For individuals **under 12**: • Supply is not available under this PGD. A child protection expert must be contacted, and the patient must be managed according to child protection protocol • **Child protection -** Consider child protection issues including child sexual exploitation (CSE) risks in all individuals under 18 and the requirement to complete the Somerset CE screening tool where risk is identified (consult with health professional with extensive experience in child protection); and the mandatory reporting requirement for disclosures of Female Genital Mutilation (FGM) for girls aged under 18 (call non-emergency '101' number by close of next working day) • **Safeguarding** – Consider safeguarding issues in all individuals age 18 and over (e.g. individuals with learning disabilities; domestic abuse) Please refer to the Somerset School Nurse Emergency Contraception Pro Forma and safeguarding guidance.

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Condition: Emergency Hormonal Contraception
Professional Group: Registered Nurses

8.	**Drug Details**	
	Name, form and strength of medicine	Levonorgestrel (LNG-EC) 1500 microgram tablet
	Legal Category	Prescription-only medicine (POM)
	Black Triangle Status	NO
	Route / method of administration	Oral
	Dosage	ONE or TWO 1500 microgram tablet
	Frequency	One x 1500mcg tablet
	Duration of treatment	• One tablet as a single dose as soon as is practicable after unprotected sexual intercourse (UPSI) • For individuals taking medication that induces hepatic enzymes one dose of TWO x 1500mcg tablets (3mg) should be taken as soon as possible after UPSI • For individuals with a BMI >26kg/m2 or weight >70kg a dose of TWO x 1500mcg tablets (3mg) should be taken as soon as possible after UPSI • If vomiting occurs within three hours of taking the levonorgestrel 1500 microgram tablet, a second supply of ONE or TWO levonorgestrel 1500 microgram tablets may be made providing the criteria of this PGD are met.
	Total dose number to supply / administer	• ONE or TWO tablets as above

9.	**Side effects**	• The most commonly reported undesirable effect is nausea (~20%) but vomiting occurs only in 1% of women • If vomiting occurs within three hours of taking the tablet the levonorgestrel 1500 microgram tablet, a second supply of ONE or TWO levonorgestrel 1500 microgram tablets may be made providing the criteria of this PGD are met. The woman needs to contact issuer of the medication for a repeat dose • Very common (~10%): bleeding not related to menses, nausea, headaches, low abdominal pain, fatigue • If women experience lower abdominal pain they must seek prompt medical help to exclude an ectopic pregnancy • Common (~1%): delay of menses more than seven days, irregular bleeding and spotting, dizziness, headache, diarrhoea, vomiting, breast tenderness • Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within seven days of the expected time • If the next menstrual period is more than five days overdue, pregnancy should be excluded For other less common side effects, please refer to the Summary of Product Characteristics (SPC) and the current version of the BNF
10.	**Reporting procedure of Adverse Reactions**	Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk
11.	**Advice to patient / carer**	• There is no day of the menstrual cycle when there can be certainty that unprotected sexual intercourse (UPSI) would not result in pregnancy, although the probability is negligible in the first three days of the cycle. • The overall risk of pregnancy after a single act of unprotected sex on a day of the menstrual cycle is 2-4% but is highest (20-30%) in the days just before and just after ovulation (i.e. days 10 to 17 of a normal 28 day cycle.) • The earlier Levonorgestrel is taken after UPSI the more effective it is. Overall, if taken within 72 hours of UPSI, Levonorgestrel prevents 84% of expected pregnancies. • Prior to treatment, the patient (or person with parental responsibility) is given the Patient Information Leaflet (PIL) from the product packaging. Confirmation must be sought that they have read and understood the PIL and consent to treatment. • Available evidence suggests that oral EC administered after ovulation is ineffective

		• Inform individual of common side effects (see above or refer to BNF or SPC) • If vomiting occurs for any reason with three hours of taking the tablet, women should contact issuer to obtain another supply of Levonorgestrel or further advice re other methods • If menstrual periods are delayed by more than seven days, or abnormal bleeding occurs (e.g. light, heavy or brief) or there is no withdrawal bleed or if pregnancy is suspected for any other reason, women should seek further medical advice for pregnancy to be ruled out • If more than one dose of Levonorgestrel is taken in the menstrual cycle, cyclical disturbance is more likely • Women who are already on hormonal contraception must be advised to resume their original contraception with appropriate advice on precautions • For women who are not on any other contraception, Levonorgestrel does not provide ongoing contraception and use of alternative methods of contraception for the rest of the cycle must be discussed. Women should be counselled on the benefits of long acting reversible contraception (LARC) and that the IUD has the lowest failure rate of all emergency contraception. Women should be offered a referral to have an IUD fitted if in appropriate timescale and the patient would prefer this. (Ref: Quick Starting Contraception guidance) • If the woman and her EC provider consider that UPSI is unlikely to have occurred during her fertile period, she may consider LNGEC and immediate start of hormonal contraception, rather than UPA-EC and delayed start of contraception. If unable to quick-start a new method, women should be advised to make a medical appointment to initiate or adopt a method of regular contraception if appropriate • If pregnancy occurs after treatment with Levonorgestrel, the possibility of ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as Levonorgestrel prevents ovulation and fertilisation. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding • Levonorgestrel should not be given to pregnant women. It will not interrupt a pregnancy after it has implanted. In the case of continued pregnancy, limited evidence suggests no adverse effects on the foetus • Levonorgestrel is secreted into breast milk. No serious adverse effects on the foetus have been reported and potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing following Levonorgestrel administration

		If under the age of 25 the benefits of chlamydia screening should be discussed and offered if appropriate. Use of emergency contraception does not replace the necessary precautions against sexually transmitted infections (STIs) • Useful contacts for patients include: ○ FPA UK (formerly Family Planning Association) – 0845 122 8690 ○ NHS Direct – 111 ○ Sexual health services in Somerset www.swishservices.co.uk or by downloading the Somerset SWISH Services app
12.	**Arrangements for follow up**	Arrange follow up in about three weeks Arrange future contraception as appropriate Discuss/offer STI/Chlamydia screening Anticoagulants – the anticoagulant effect of warfarin and phenindione is enhanced: the patient should be referred to their GP to ensure follow-up and INR is checked three-days after POEC After taking LNG-EC, women should be advised to start suitable hormonal contraception immediately. Women should be made aware that they must use condoms reliably or abstain from sex until contraception becomes effective

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Referral Arrangements and Audit Trail		
13.	**Referral arrangements**	• For IUD up to 120 hours emergency contraception refer to GP or Somerset-wide Integrated Sexual Health Service (SWISH) as appropriate • For ulipristal acetate over 96 hours to 120 hours refer to Pharmacist (participating pharmacies can be found on www.swishservices.co.uk or the SWISH Services app • For ongoing contraceptive care refer to GP or SWISH • **Late period / abnormal bleeding** - Patients should consult a GP, or a relevant specialist service if the patient's next period is seven or more days late or if abnormal bleeding occurs • **Sexually transmitted infections** (STIs) - Refer patient to GP, or sexual health service for evaluation / treatment if the presence of an STI is known or suspected • **Chlamydia screening** – If aged between 15 and 24 years offer chlamydia screening kit • **Anticoagulants** – The anticoagulant effect of warfarin and phenindione is enhanced: the patient should be referred to their treating doctor to ensure follow-up and INR is checked three-days after EHC • **Lower abdominal pain** - If any lower abdominal pain occurs, the patient should seek further medical evaluation (because the pain may signify an ectopic pregnancy) • **Sexual health app** – nurses should make use of the Somerset sexual health app to provide information to patients about other sexual health services available
14.	**Record specific information for the supply/administration of medicines to include details for audit trail and significant events**	It is essential to record the following in the patient notes: • Patient's name/address/date of birth and consent • Indications for use • Advice given to patient/carer (to include side effects) • Brand, batch number and expiry date of medicine • Name of medicine / dose / quantity supplied • Signed and dated. (Where computer records are used nurses/health professionals must have individual identifier to enable audit trail)

		• Document any adverse reactions • Where a child is not accompanied by a person with parental responsibility the name and relationship of any person bringing the child for treatment should be recorded along with confirmation that the consent of a person with parental responsibility has been obtained • For individuals aged under 16: a statement as to the 'Fraser' competence of the individual • For children under 13 years of age: details of the discussion with the safeguarding expert prior to consideration of supply • For individuals with a BMI ≥ 26kg/m^2 or body weight >70kg, this is to be recorded The Somerset School Nurse Emergency Contraception Pro Forma should be used to record details of EHC consultations All significant events/incidents/near misses occurring in relation to the supply/administration of a medicine under this PGD must be reported on the relevant incident form in a timely manner.

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Professional Group: Registered Nurses

Staff Characteristics	
Professional qualifications	Nursing and Midwifery Council (NMC) Registered Nurses and Midwives
Specialist competencies or qualifications	• The healthcare professional has undertaken appropriate training and assessed as competent to carry out clinical assessment of a patient leading to diagnosis that requires treatment according to the indications listed in this PGD • The healthcare professional has undertaken approved training and competency assessment in the supply or administration of medicines under PGDs • You must be authorised by name, under the current version of this PGD before working under it
Continued education & training	• PGD training and theory competency assessment • Competency assessment for this PGD • Successful completion of any medicine's management and drug calculation training and competency assessment required for the relevant professional group and area of practice as required • It is the healthcare professional's responsibility to maintain their competency and ensure that they have access to up to date information and reference sources
Additional Requirements	Healthcare Professional to complete Individual Authorisation signed by authorising manager. Copy to be kept by authorising/line manager in department and copy to individual nurse

References / Resources and comments

BNF 71 (2016) British National Formulary.71st edn. London: British Medical Association and Royal Pharmaceutical Society of Great Britain) Available from: https://bnf.nice.org.uk/drug/levonorgestrel.htmls (accessed 12/03/2019)

Clinical and quality care commission (2018), Nigel's surgery 8: Gillick competency and Fraser guidelines. Available from: https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-8-gillick-competency-fraser-guidelines (accessed 12/03/2019)

Faculty of Sexual and Reproductive Healthcare (2017) Emergency Contraception guideline. Available from: https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ (accessed 12/03/2019)

Faculty of Sexual and Reproductive Healthcare (2017) Emergency Contraception guideline. Available from: https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/combined-hormonal-contraception/ (accessed 12/03/2019)

National Institute of Clinical Excellence (2019) Contraceptive services for under 25s- Recommendation 8 Providing school and education-based contraceptive services, London: NICE. Available from: https: https://www.nice.org.uk/guidance/ph51/chapter/1-Recommendations#recommendation-8-providing-school-and-education-based-contraceptive-services (accessed 12/03/2019)

National Institute of Clinical Excellence (2017), Clinical Knowledge Summaries, London: NICE. Available from: https://cks.nice.org.uk/contraception-emergency (accessed 12/03/2019)

Somerset Locality Safeguarding Children Board – Guidance for Child Sexual exploitation - https://sscb.safeguardingsomerset.org.uk/working-with-children/cse-protocols/

Medicine Management Policy – Public Health Somerset County Council 2019.

This Patient Group Direction is to be read in conjunction with the following policies:

Somerset County Council medicines policy

The following PGDs were read as part of the development of this PGD:

Somerset Partnership NHS Foundation Trust Patient group direction 9.1 Levonorgestrel (LNG-EC) 1500 microgram

Somerset County Council Patient Group Direction for the pharmacist supply of Levonorgestrel

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This patient group direction must be agreed to and signed by all health care professionals involved in its use. Somerset County Council should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Organisation	

Authorisation	**Signature** **Date**
Nominated GP	Andrew Tresidder DR. ANDREW TRESIDDER GP. GMC 2823735 10 April 2019
Director of Public Health	 10 April 2019 **Trudi Grant, MSc PH, UKPHR, FFPH** **Director of Public Health** Somerset County Council
Senior Pharmaceutical Advisor	REBECCA MYERS 2049387 10 April 2019
Consultant Microbiologist **(for Antibiotics)**	N/A

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Individual Authorisation

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.

Note to Authorising Managers: 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 supply / administer this medicine only in accordance with this PGD.

Location:				
Name of Professional	**Professional registration no. (pharmacists only**	**Signature**	**Authorising Manager[1]**	**Date**

Please ensure a copy of this page is kept by the Line Manager.

Appendix One – Uncommon and rare side effects

System Organ Class	Adverse Drug Reactions