# Patient Group Direction for the supply and/or administration of Levonorgestrel 1500mcg tablet to patients receiving treatment from NHS Borders.

**This document authorises the supply and/or administration of Levonorgestrel 1500mcg tablet by registered pharmacists to patients who meet the criteria for inclusion under the terms of the document.**

**The registered pharmacist seeking to supply and/or administer Levonorgestrel 1500mcg tablet must ensure that all patients have been screened and meet the criteria before supply takes place.**

**The purpose of this Patient Group Direction is to allow management of Levonorgestrel 1500mcg tablet in NHS Borders by those registered Health professionals that are listed and approved in legislation as able to operate under Patient Group Directions.**

**PGD previously approved: November 2018**

**This direction was authorised: November 2021**

**The direction will be reviewed by: November 2024**

**Author of PGD: Adrian MacKenzie, Lead Pharmacist, Community Pharmacy**

**Clinician Responsible for Training and Review: Adrian MacKenzie, Lead Pharmacist, Community Pharmacy**

**Specialist review: Sally Wielding, Consultant in Sexual and Reproductive Health; Dawn MacBrayne Prescribing Support Pharmacist**

**Patient Group Direction (PGD) for community pharmacists working in NHS Border pharmacies on the supply of levonorgestrel 1500microgram (mcg) tablet for Emergency Hormonal Contraception**

**1. This PGD relates to the following specific preparation**

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| Name, form and strength of medicine | Levonorgestrel 1500 microgram (mcg) tablet (LNG)<br><br>**Note:** This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to.<br><br>**Levonorgestrel 1500 (mcg) tablet is the 2nd line product for emergency hormonal contraception. Only supply LNG using this PGD if the woman is not suitable for UPA. See the UPA guidance for full details of exclusions, cautions in use, warnings and additional information.** |
| Legal status | Prescription Only Medicine (POM) |
| Storage | Store in original container below 25°C |
| Dose, frequency and route of administration | One tablet taken as a single oral dose as soon as possible, but no later than 72 hours after unprotected sexual intercourse (UPSI) or contraceptive failure.<br><br>If vomiting occurs within 3 hours of taking the original dose, another tablet should be taken immediately so an additional further dose can be supplied under this guidance.<br><br>Women using liver enzyme-inducing drugs (see below) can be given TWO tablets but should be informed that the effectiveness of the regimen is unknown (see below for further details).<br><br>LNG can be taken again after further UPSI in the same cycle. |
| Verbal advice to be given | Discuss the mode of action, failure rate and possible effects on the foetus of LNG. If pregnancy is a possibility this should be excluded before supply is made. |

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| | Offer LNG on any day of the natural menstrual cycle but advise that is is unlikely to be effective if taken after ovulation.<br><br>Advise all women, in particular those using liver enzyme-inducing drugs that a copper intrauterine device (Cu-IUD) is the preferred option. Pharmacists can refer directly to Borders Sexual Health (BSH) by telephoning 01896 663700. There is no provision for Cu-IUD insertion at BSH on Saturday and Sunday so please phone ward 16 at BGH if required on 01896 826016. Some GP practices may be able to offer urgent Cu-IUD fitting.<br><br>For women who have missed their oral contraceptive pill, provide information as outlined by the Faculty of Sexual and Reproductive Health (FSRH) guide on "Indications for emergency contraception following potential failure of hormonal and intrauterine methods of contraception at: https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ (page 5).<br><br>If the woman is taking the oral contraceptive pill or using the contraceptive patch and EHC is required, advise her to use a barrier method in addition to her usual method for 7 days.<br><br>If the woman is not using an oral contraceptive pill, a barrier method of contraception should be used until appropriate contraceptive advice from BSH or GP is given.<br><br>Advise all women that higher weight or body mass index (BMI) could reduce the effectiveness of oral EHC. Women should be informed that the effectiveness of the Cu-IUD is not known to be affected by weight or BMI.<br><br>Advise that LNG is for occasional use only and should not be used as a replacement for a regular contraceptive method. Provide local information about how to access BSH and contraceptive advice.<br><br>Highlight that the woman's next period may be early or late. It is important that the woman is aware of this risk and advised regarding ongoing reliable contraception.<br><br>Advise what to do if vomiting occurs within 3 hours of taking the medicine.<br><br>Advise to seek medical advice immediately if experiencing lower abdominal pain or abnormal bleeding.<br><br>Breastfeeding is not thought to be harmful but |

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| | potential exposure can be reduced if the woman takes the dose immediately after feeding and avoids breastfeeding for at least 8 hours following administration. |
| Written Information | Provide the manufacturers Patient Information Leaflet (PIL) for LNG.<br>Written information about locally available contraception services and methods of contraception.<br>Written information about locally available services providing sexual health advice. |
| Documentation | The pharmacist must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. |
| Follow-up advice | Advise that they should consider being tested for a sexually transmitted infection and provide local information about where they can obtain that service.<br>Advise that if they have not had their period within 5 days of their expected date of menstruation, abnormal bleeding occurs or pregnancy is suspected, they should carry out a home pregnancy test, contact BSH or GP to discuss, this is to confirm or exclude pregnancy.<br>Advise attendance at BSH or GP practice for ongoing contraceptive advice. |
| Consent for adults | Prior to the supply of LNG consent must be obtained, preferably in writing.<br>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.<br>Provide information 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 16's | A woman under 16 years of age may give consent for the supply of EHC, provided she understands fully the benefits and risks involved. She should be encouraged to involve a parent/guardian, if possible, in this decision.<br>Where there is no parental involvement and the woman indicates that she wishes to accept the supply, supply should proceed, if the pharmacist deems that she has the legal capacity to consent.<br>The Age of Legal Capacity (S) Act 1991, s2(4) states |

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| | 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.'<br><br>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. |
| Warnings/additional information | **Reduced efficacy of LNG**<br>The metabolism of LNG is enhanced by concomitant use of liver enzyme inducers, (and for at least 4 weeks after stopping), and these medicines can reduce the efficacy of LNG. These include: rifampicin, phenytoin, barbiturates (including primidone), carbamazepine, efavirenz, rifabutin, St John's wort/Hypericumperforatum, ritonavir, griseofulvin.<br><br>• LNG may increase the risk of cyclosporin activity due to possible inhibition of cyclosporin metabolism.<br><br>A Cu- IUD is the preferred option. TWO tablets of LNG given as a single dose is an unlicensed indication but it is a recommendation of the FSRH.<br><br>**Common side effects include:**<br>Headache, dizziness, fatigue, menstrual irregularities, nausea, vomiting, low abdominal pain, breast tenderness, diarrhoea.<br><br>**This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.**<br><br>BNF:<br>https://www.bnf.org/products/bnf-online/<br><br>SmPC:<br>https://www.medicines.org.uk/emc/ |

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| | HIV Drug Interactions website: www.hiv-druginteractions.org |
| Documentation | All suspected serious reactions should be reported directly to MHRA/Commission on Human Medicines through the Yellow Card Scheme and recorded in the woman's notes. Reports should be made online at www.mhra.gov.uk/yellowcard. Advice may be obtained from the Yellow Card Centre Scotland on 0131 242 2919.<br>The pharmacist must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. |
| Follow-up | None required. |

**Clinical condition**

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| Clinical condition or situation | Woman presenting in person at the community pharmacy requesting emergency contraception for their own use within 72 hours of unprotected sexual intercourse (UPSI) or contraceptive failure. |
| Inclusion Criteria | Any woman 13 years or over.<br><br>UPSI/contraceptive failure within the last 72 hours.<br><br>UPSI/contraceptive failure within the last 72 hours where the woman has vomited within 3 hours of taking a dose of LNG for EHC.<br><br>Woman has no contra-indications to LNG.<br><br>Woman gives their consent to providing the relevant clinical information to the pharmacist after the pharmacist has assessed their capacity to consent.<br><br>Woman is excluded from using UPA. |
| Exclusion Criteria | Woman is suitable for UPA.<br><br>UPSI/contraceptive failure more than 72 hours prior to presentation.<br><br>Woman has already taken UPA within the previous 5 days.<br><br>Unexplained vaginal bleeding.<br><br>Pregnancy known or suspected. |

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| | Current severe liver disease including jaundice.<br><br>Severe malabsorption syndromes e.g. severe diarrhoea or Crohn's disease.<br><br>Porphyria<br><br>Hereditary problems of galatcose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption. Known hypersensitivity to LNG or any other excipient in the capsule (e.g. lactose, gelatin). Consult the SPC or manufacturer's PIL.<br><br>History of salpingitis or ectopic pregnancy.<br><br>Women who have delivered a baby within last 3 weeks.<br><br>Woman 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.<br><br>Woman who the pharmacist has assessed as not being competent to consent.<br><br>Woman does not agree to share relevant clinical information or there is no valid consent. |
| Action if Excluded | Do not supply LNG<br><br>Discuss reasons for exclusion and alternative contraception and refer to BSH (01896 663700) or GP practice/BECS. The local direct referral process should be used during out of hour's period.<br><br>Document all actions taken.<br><br>Inform GP with woman's client's permission. |
| Action if patient declines treatment | Advise of the risks of the consequences of not receiving treatment.<br><br>Record outcome in Patient Medication Record if appropriate and refer the woman to their appropriate/preferred health provider using the local direct referral process if during the out of hour's period.<br><br>Document all actions taken.<br><br>Inform GP with woman's permission. |

**3. Documentation/Record keeping.**

**a) The following records should be kept (either paper or computer based)-**

The GP practice, clinic, hospital, and ward or department
The patient name and CHI number
The medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered
Drug batch number and expiry
The signature and printed name of the healthcare professional who supplied or administered the medicine
The patient group direction title and/or number
Whether patient met the inclusion criteria and whether the exclusion criteria were assessed
Quantity supplied / received and current stock balance

**b) Preparation, audit trail, data collection and reconciliation-**

Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient by patient basis.

**c) Storage-**

Medicines must be stored securely according to national guidelines and in accordance with the product SmPC

**4. Professional Responsibility.**

- All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate.
- Pharmacist must be registered with the GPhC.
- It is the responsibility of the pharmacist using this PGD to ensure that they are using the most recent issue. This can be found on the NHS Borders website at http://www.nhsborders.scot.nhs.uk/patients-and-visitors/our-services/pharmacies/community-pharmacy/community-pharmacy-pgds/

**5. References:**


- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 Updated December 2020 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/
- Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/

❖ Borders Joint Formulary (BJF) http://www.nhsborders.scot.nhs.uk/patients-and-visitors/our-services/general-services/medicines-and-prescribing/nhs-borders-formulary/

❖ Yellow Card Scheme available at: www.mhra.gov.uk/yellowcard

❖ EHC Learning module developed by NES Pharmacy which can be found at: http://www.nicpld.org/online/contraceptionnes/#mO-introduction

❖ Borders Sexual Health http://www.borderssexualhealth.org.uk/

**Patient Group Direction for the supply and/or administration of Levonorgestrel 1500mcg tablet by registered pharmacistsworking in NHS Border pharmacies**

| This Patient Group Direction is approved for use by the under-signed : | | | |
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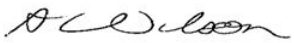
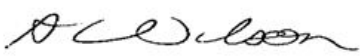
| **Job Title** | **Name** | **Signed** | **Date** |
| **Senior Doctor/Dentist for relevant clinical area** | Dr Lynn McCallum |  | 21/10/2021 |
| **NHS Borders Director of Pharmacy** | Alison Wilson |  | 27/09/2021 |
| **NHS Borders Senior Health Professional for Clinical Area** | Sarah Horan |  | 27/09/2021 |
| **PGD AUTHORISED ON 21/10/2021**<br>**Signed by ADTC CHAIRPERSON:**  <br>**Name: Alison Wilson** | | | |

**The Health Professionals named below, based at**
*(*Clinic OR GP Employer Name*)*
**are authorised to provide this medication under this Patient Group Direction and agree to provide this medication in accordance with this Patient Group Direction**

| Name of Health Professional | Job Title | Signed | Date |
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