Leeds Community Healthcare NHS Trust

Patient Group Direction for the administration or supply of Levonorgestrel Emergency Contraception for Community Pharmacy

Author	Chris Toothill (Medicines Management Pharmacist, Governance and Risk , Leeds Community Healthcare NHS Trust)
Corporate Lead	Dr Ruth Burnett (Medical Director LCH)
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Identified lead for monitoring/review and contact details	Chris Toothill (0113 2208534)
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Consultation Process adopted in developing the Patient Group Direction (PGD)

Title of document	**Patient Group Direction for the administration or supply of Levonorgestrel Emergency Contraception for Community Pharmacy**
New Document	No
Revised Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Revised due to expiry of previous version
Director Lead (name and job title)	Dr Ruth Burnett (Medical Director, LCH)
Author (name and job title)	Chris Toothill (Medicines Management Pharmacist, Governance and Risk , Leeds Community Healthcare NHS Trust)
List of persons/groups involved in developing PGD (including job title)	Dr Manisha Singh (Consultant Reproductive Sexual Health and Community Gynaecology, Leeds Sexual Health Service)
List of persons involved in consultation process (including job title)	Dr Farah Chaudhry (Consultant, Leeds Sexual Health Service) Sarah Davy (Senior Sexual Health Nurse and Medicines Management, Leeds Sexual Health Service) Lisa Meeks (Service Implementation & Evaluation Lead, Community Pharmacy West Yorkshire) Melissa Burnley (Head of Services, Community Pharmacy West Yorkshire)

Patient Group Direction for the administration or supply of Levonorgestrel Emergency Contraception for Community Pharmacy	
Applies to:	Pharmacists currently registered with the General Pharmaceutical Council of Great Britain and: • Have demonstrated they are competent to provide the service by completion of an up-to-date (i.e. completed within the last 3 years) Declaration of Competence for Emergency Contraception Services hosted by The Centre for Pharmacy Postgraduate Education.
Clinical Condition	
Condition	Provision of emergency contraception (EC) to females of reproductive age who are at risk of unwanted pregnancy and present within 72 hours following unprotected sexual intercourse (UPSI) or contraceptive failure.

Inclusion criteria	• Exposure to risk of pregnancy following unprotected sexual intercourse (this includes failure of barrier methods of contraception or reduced efficacy of a contraceptive method)
	• All females aged 13 years and over. If the female is under 16 years of age they must be competent under Fraser Guidelines and child protection issues must be considered for under 18s.
	• If the female is over 18 then safeguarding may need to be considered in vulnerable individuals
	• Verbal consent needs to be obtained from patient prior to treatment.
	• Levonorgestrel should be used as a method of Emergency Hormonal Contraception only after consideration of:
	  ○ Use of a Copper Intra-Uterine Device (Cu-IUD) has been discussed with the female and declined or contra-indicated and
	  ○ Ulipristal is contra-indicated , has a potential drug interaction or, after discussion with the female she expresses a preference for levonorgestrel

Exclusion criteria	• Clients not competent to give consent under the Mental Capacity Act • Clients under 13 years of age • Clients under 16 and who do not satisfy Fraser Guidelines • Pregnancy or suspected pregnancy • Presentation more than 72 hours after UPSI or contraceptive failure • Any client having taken ulipristal previously within the current cycle (a further supply of levonorgestrel may be made in the same cycle if levonorgestrel was taken for the previous episode of UPSI). • Hypersensitivity to Levonorgestrel or any components of the tablet • Severe hepatic dysfunction, severe malabsorption syndromes (such as Crohn's disease) • Patient's with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption • Trophoblastic disease • Active acute porphyria • Unexplained Vaginal bleeding • Less than 21 days post-partum • Presence of any contraindication as detailed in the current Summary of Product Characteristics (SPC)
Action if excluded or does not consent	Consider if supply of ulipristal would be a suitable alternative. Advise of possible alternative methods of contraception and refer to a Leeds Sexual Health Service or GP. If treatment is declined, offer advice on the risk of pregnancy and recommend a pregnancy test if menstrual bleeding is overdue or lighter than usual. Document reasons for exclusion or non-consent. If under 13 years of age local safeguarding procedures must be followed and the relevant authorities informed.

Description of Treatment

Name of medicine	Levonorgestrel 1500 microgram
Legal classification	Prescription only medicine (POM)

Licensing information	The product is licensed for the indication in this PGD This PGD also includes unlicensed use (Faculty of Sexual and Reproductive Healthcare Clinical Guidance – Emergency Contraception March 2017 (amended December 2017)) i.e. • That it can be given more than once in a cycle • Double dose may be given if the client is on liver enzyme inducing medication (see section on drug interactions for further information) • Double dose may be given for its potential ability to prevent unintended pregnancy more effectively than the standard 1500 microgram dose in clients weighing >70 kg or with a BMI >26 kg/$m^{2.}$
Form	Tablet
Strength	1500 micrograms
Dose	1500 micrograms of Levonorgestrel (one tablet) taken as soon as possible, and no later than 72 hours after unprotected intercourse. If the client vomits within three hours of taking the tablet a repeat dose may be given. Where a client is taking enzyme inducing drugs, and for up to 4 weeks after stopping, or a client weighs>70 kg or with a BMI >26 kg/m^2 the dose may be doubled to 3000 micrograms (two tablets).
Maximum dose	Single dose of Levonorgestrel 1500 micrograms (one tablet) but if the client is taking or has taken a liver enzyme inducing drug within the last four weeks or a client weighs>70 kg or with a BMI >26 kg/m^2 3000 micrograms (two tablets) should be taken. The two tablet dose (3000 micrograms) for clients taking a liver enzyme inducing drug or clients weighing>70 kg or with a BMI >26 kg/m^2 should only be offered after; a Cu-IUD has been discussed as the most effective method to avoid pregnancy, and declined or not appropriate, and then Ulipristal Acetate considered and declined or not appropriate.

Route	Oral
Total treatment quantity	If there is more than one risk per cycle, Levonorgestrel 1500 micrograms may be supplied on two occasions in one cycle. If Ulipristal Acetate has been given in the current cycle previously Levonorgestrel cannot be given.
Adverse reactions	Very Common (≥ 1 in 10) and Common (≥ 1 in 100 to < 1 in 10) adverse reactions include: • Nausea, vomiting, diarrhoea, lower abdominal pain • Menstrual cycle may be temporarily disturbed most females will have their next menstrual period within 5 days of the expected time • Some females experience bleeding or spotting before their next menstrual period • Other side effects include breast tenderness, headache, dizziness fatigue This list is not exhaustive; refer to individual SPC for further information. For full details of side effects, the product literature should always be consulted. Report **all serious suspected** adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA), Commission on Human Medicine using a Yellow card or on-line via www.yellowcard.gov.uk. Report serious or suspected reactions even if they are listed above, in the BNF or in the Summary of Product Characteristics (product data sheet). Yellow cards may be completed by a nurse, pharmacist, the patient or a doctor. Serious reactions are those that are fatal, life threatening, disabling, incapacitating or which result in or prolong hospitalisation and / or are medically significant.
Drug Interactions	The metabolism of Levonorgestrel is enhanced by concomitant use of liver enzyme inducers, mainly CYP3A4 enzyme inducers Liver Enzymes inducing drugs include: Antiepileptics - phenobarbital, primidone, carbamazepine, phenytoin, fosphenytoin, topiramate, oxcarbazepine, eslicarbazepine, perampanel, rufinamide Antifungals – griseofulvin Antibacterials – rifampicin, rifabutin Antivirals – nevirapine, atazanavir, efavirenz, bocepevir,ritonavir Herbal medicines containing Hypericum perforatum (St. John's Wort), (This is not an exhaustive list always check current BNF and product SPC)
Storage Requirements	Store in original packaging in order to protect from light.

Written and oral advice and necessary follow-up	1. Explain the following: • Treatment and course of action • Efficacy – hormonal emergency contraception is not 100% effective. It will prevent about 95% (19 in 20) of expected pregnancies if taken within 24 hours of unprotected intercourse, 85% (17 in 20) if taken between 24-48 hours after intercourse and 58% (approximately 11 in 20) if taken between 48 and 72 hours after intercourse. Hormonal emergency contraception is unlikely to be effective if taken after ovulation • **Use of a Copper Intra Uterine Device (Cu-IUD) must always be discussed and considered as this is the most effective form of emergency contraception**. If a Cu-IUD is chosen by the client, a supply of levonorgestrel must still be offered if clinically appropriate, and referral made to a Sexual Health Service or GP. • Risks and side-effects. Encourage the client to report any side-effects to you, a Sexual Health Service or GP • Possible effects on menstrual cycle • Following administration of levonorgestrel clients continuing to use a hormonal method of contraception should be advised to use additional precautions for 7 days for combined hormonal methods, 2 days for progesterone only contraceptives and 9 days for Qlaira®. • If not currently using hormonal contraception, the need to abstain from sex or use barrier methods correctly and consistently for the remainder of the current menstrual cycle - emergency contraception does not protect against unprotected intercourse in the rest of the cycle. EHC can delay ovulation and move the fertile period on by five days increasing the risk of pregnancy later in the cycle • If unprotected intercourse occurs she should return promptly for further advice, or contact a Sexual Health Service, or GP. Supply condoms if required. • That, although there is no evidence that oral emergency contraception carries any risk of teratogenicity, a normal outcome to any pregnancy cannot be guaranteed. Provide the manufacturer's patient information leaflet 2. Advise the female that: • If she vomits within three hours of taking the tablet she should return promptly for further advice and a further supply, or contact a Sexual Health Service or GP. • If the next menstrual period is more than five days late or is unusual in any way (e.g. is lighter, shorter or later than usual) the client should return or visit Sexual Health Service or GP to have a pregnancy test in three weeks • Emergency Contraception does not protect against sexually transmitted infections and advice on necessary precautions should be given • To see her GP or a Contraception and Sexual Health Service for Long Term Contraceptive Advice • Provide information about local services for on-going contraceptive information and supply, and infection screening as necessary

Record keeping	The following must be recorded:
	• Patient's name, address, date of birth and consent given.
	• Assessment of patient need in relation to the intervention including:
	  ○ Patient history
	  ○ Date of last menstrual cycle
	  ○ Possibility of pregnancy
	  ○ Inclusion criteria
	  ○ Criteria for referral
	• An assessment of the patients understanding of the treatment (if under 16 years) – i.e. they are competent under Fraser Guidelines
	• Actions taken if a child protection issue is identified or suspected
	• Date and time of supply
	• Brand name of the product
	• Batch number and expiry date
	• GPhC registration number of the pharmacist who supplied the medication
	• Information given to the patient
	• Details of any adverse drug reactions and actions taken
	• Any other details as required by the service specification

References	• British National Formulary - update on line edition, accessed 4 September 2019 2016 • Bayer PLC: Levonelle -1500® Summary of Product Characteristics. www.medicines.org.uk (last updated 9 Jun 2019) accessed 4 September 2019 • Faculty of Sexual & Reproductive Healthcare Emergency Contraception (March 2017 – amended December 2017) • NHS Executive HSC 2000/026. Patient Group Directions [England only] London 2000 • Faculty of Sexual & Reproductive Healthcare, UK Medical Eligibility Criteria (UKMEC) (April 2016 amended November 2017) • National Institute for Health and Care Excellence- Contraceptive Service for under 25s Public Health Guidance PH 51 – March 2014)

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Name of Pharmacy	

Professionals to whom this Patient Group Direction applies:

- I have read and understood this Patient Group Direction and any associated guidance and agree to supply and/or administer this medicine only in accordance with this
- It is my responsibility to practice only within my bounds of competence and in accordance with my Code of Professional Conduct

Patient group Directions do not remove inherent professional obligations or accountability

Name(s) of Pharmacist (s) CAPITALS	**Signature(s) of Pharmacist**	**GPhC Number**	**Date**

Authorisation for Community Pharmacy Authorising Manager* designated lead (must be a pharmacist)

I hereby authorise the above named pharmacists to carry out this activity as stated in the Patient Group Direction.

a. is aware of the service specification and requirements for provision of the service;

b. has completed the Declaration of Competence (DoC) self-assessment framework within the last 3 years and has printed and signed the statement of declaration; and

c. confirm that the pharmacist has the organisation's approval to provide the service.

I agree to maintain a current list of the names of individuals who may implement this PGD and keep this with a pharmacy master copy of the PGD

* In certain circumstances, for example, a community pharmacy where the pharmacist who will administering Levonorgestrel is also the superintendent pharmacist or contractor, it may be necessary for the authorising manager to be the same person as the practitioner, though this situation should be avoided wherever possible

Name	**Signature**	**Date**

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Produced by Leeds Community Healthcare NHS Trust on behalf of Community Pharmacies in Leeds commissioned to provide this service			
Name	**Designation**	**Signature**	**Date**
Chris Toothill	Medicines Management Pharmacist (Governance and Risk)	**On File**	**24/06/2020**
Dr Manisha Singh	Consultant Leeds Sexual Health Service	**On File**	**24/06/2020**

Approved for use within Community Pharmacies in Leeds commissioned to provide this service			
Name	**Designation**	**Signature**	**Date**
Dr Ruth Burnett	Medical Director Leeds Community Healthcare	**On File**	**08/07/2020**

PGD authorisation and adoption by Leeds City Council for use within Community Pharmacies in Leeds commissioned to provide this service			
Name	**Designation**	**Signature**	**Date**
Victoria Eaton	Director of Public Health, Leeds City Council	**On File**	**03/07/2020**