Patient Group Direction for the supply of:

Levonorgestrel 1.5mg Tablet

(Brands include Levonelle® 1500 / Upostelle®)

By accredited pharmacists in Sheffield community pharmacies, commissioned by Sheffield City Council to provide sexual health services

Issue Date: March 2018
Review date: November 2019
Expiry Date: March 2020

Sponsored by: Greg Fell, Director of Public Health

Sheffield Community Pharmacy Sexual Health Services

Patient Group Directions (PGDs) are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

Date this Patient Group Direction comes into effect:	**1 March 2018**
For the supply of:	**Levonorgestrel 1.5mg tablet** (Brands include Levonelle® 1500 / Upostelle®)
Class of health professional who may supply:	A registered pharmacist who has received appropriate training and has been approved as competent to supply levonorgestrel 1.5mg tablet in accordance with the following patient group direction. See Appendix 1 for training requirements.

PATIENT GROUP DIRECTION
Levonorgestrel 1.5mg Tablet
(Brands include: Levonelle® 1500 / Upostelle®)

Sheffield City Council PGD (Approved: March 2018 Expiry: March 2020)

PATIENT GROUP DIRECTION for the supply of: Levonorgestrel 1.5mg tablet

PGD Development and Approval

Developed by:	Signature	Date
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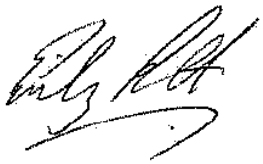
Lead pharmacist **Emily Pratt** GPC no. 2061429 Medicines Management Pharmacist NHS Sheffield CCG		26/02/18
Peer review Claire Thomas GPC no. 2058199 Chief Officer Community Pharmacy Sheffield		26/02/18
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Approved on behalf of Sheffield City Council by:	Signature	Date:
Greg Fell Director of Public Health Sheffield City Council		26/02/18
Expiry date:	**31st March 2020**	

PATIENT GROUP DIRECTION
Levonorgestrel 1.5mg Tablet
(Brands include Levonelle® 1500 / Upostelle®)

Sheffield City Council PGD (Approved: March 2018 Expiry: March 2020)

Clinical condition or situation to which the direction applies	
Indication	Emergency contraception (EC) for circumstances of unprotected sexual intercourse (UPSI), defined as no contraception used or contraception used incorrectly. Note: a post coital copper intrauterine device (Cu-IUD) is the most effective emergency contraceptive and an oral EC is indicated where the patient is ineligible for or declines this. Levonorgestrel 1.5mg should also be administered under this PGD where the young woman is referred on for a Cu-IUD in case this cannot be inserted or she changes her mind. See EC decision tree, including choice of oral EC and where ulipristal acetate is preferred.

Criteria for inclusion	Request from a young woman at risk of pregnancy* who gives informed consent for emergency contraception within 96 hours of earliest risk by
	• Any female aged 16 and 17 years
	• Any female aged 14 - 15 years (inclusive) who is deemed to be Fraser competent; clients aged less than 16 years must be offered the opportunity to seek parental consent prior to treatment.
	• Risk may be related to
	  ○ No contraception used
	  ○ Failure of barrier method of contraception
	  ○ Reduced efficacy of contraceptive method. Refer to Faculty of Sexual & Reproductive Healthcare guideline (see Table 1). Examples include:
	  ▪ Missed taking the contraceptive pill* or patch
	  ▪ Severe diarrhoea and vomiting which may have reduced oral contraceptive efficacy
	  ▪ More than 14 weeks have elapsed since the last medroxyprogesterone acetate depot injection
	  ▪ Complete or partial expulsion of IUD
	  ▪ Vomiting within 3 hours of taking levonorgestrel emergency contraceptive pill
	*For missed or late combined contraceptive pills, see Appendix 3 flow chart.
	
	Off label inclusions *(can be used to supply and/or administer outside the terms of the SPC (summary of product characteristics) provided that such use is supported by evidence and best clinical practice).*
	• Request for emergency contraception between 72 and 96 hours after UPSI.
	• Request for emergency contraception where previous risks have occurred in the same cycle.
	• Request for emergency contraception more than once in the same cycle.
	• Double dose to women weighing >70 kg or with a BMI >26 kg/m^2.
	• Request for emergency contraception when woman is at risk of an ectopic pregnancy (previous history of salpingitis or of ectopic

	pregnancy); she should be advised to see her GP or Sexual Health Sheffield for follow up.
Criteria for exclusion	• Lack of valid consent or Fraser competency • Ulipristal acetate has been used previously in the same menstrual cycle • Known allergy to the active ingredient levonorgestrel or any excipients. • Pregnancy or suspected pregnancy. • Unexplained vaginal bleeding. • Current breast cancer. • Active trophoblastic disease. • Acute porphyria. • Active liver disease. • Severe malabsorption (e.g. Crohn's disease). • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption • Patients taking ciclosporin
Action if excluded	Refer the client to her General Practitioner or to Sexual Health Sheffield service in the following circumstances: • If any criteria for exclusion applies and ulipristal acetate is not suitable • If <16 years and is not deemed to be Fraser competent • If menstrual bleeding is overdue – a pregnancy test can be offered and EC given if the result is negative but referral for follow up should still occur • If the LMP was abnormal in timing or character • If pregnancy is suspected for any other reason • If the client has had unprotected intercourse more than 96 hours earlier in the same menstrual cycle where EC was not used. They should be informed that a Cu-IUD can be inserted up to 5 days after the first UPSI in a natural menstrual cycle, or up to 5 days after the earliest likely date of ovulation (whichever is later). Ulipristal acetate is available up to 120 hours after UPSI and may be supplied if not contraindicated (refer to ulipristal guideline).
Arrangements for referral or for seeking further advice	Give the client a Star Card to enable them to access SHS Fast Track scheme and SHS contact details. http://www.sexualhealthsheffield.nhs.uk/ A list of GP practices that provide IUD fitting is available on the SHS website http://www.sexualhealthsheffield.nhs.uk/services/contraception-service/gp-contraception-services/ If the client's surgery is not listed, her GP may be able to refer to a neighbouring surgery that offers this form of contraception. Ensure client is aware of need to attend as soon as possible.
Additional Information	Where the patient is below 16 year of age, competence under the "Fraser guidelines" must be assessed and documented. **Effect of body weight** Where the patient weighs over 70kg or with a BMI > 26kg/m^2 they should be informed that the efficacy of the CU-IUD device is not affected by

	weight and is the most effective form of emergency contraception, irrespective of body weight. The evidence suggests that ulipristal acetate may be slightly more effective than levonorgestrel and is preferred in this group of patients. If this is not suitable, a double dose (3 mg) of levonorgestrel may be used off label, although its effectiveness for these women has not been established. For women weighing >85 kg or with a BMI >30 kg/m^2, it is not known whether ulipristal acetate or 3 mg levonorgestrel is more effective.
References	1. BNF February 2018. Current BNF is available at: https://www.medicinescomplete.com/mc/bnf/current/ 2. Summary of Product Characteristics (SPCs) for Levonorgestrel 1.5mg Tablet available at: https://www.medicines.org.uk/emc/ 3. Faculty of Sexual and Reproductive Health Care (FSRH) Guideline Emergency Contraception, March 2017 (updated Dec 2017) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf 4. FSRH Clinical Guidance Drug Interactions with Hormonal Contraception January 2017 http://www.ffprhc.org.uk/pdfs/CEUGuidanceDrugInteractionsHormonal.pdf 5. FSRH Clinical Effectiveness Unit Missed Pill Recommendations (May 2011) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-statement-missed-pills-may-2011/ 6. NICE guidelines MPG2 Patient Group Directions March 2017 Using PGDs Section 1.5 https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations#using-patient-group-directions Acknowledgement STH Sexual Health Sheffield PGD for supply of levonorgestrel 1.5mg tablet (PGD 318 v5)

Description of Treatment	
Name, strength & formulation of drug	Levonorgestrel 1.5mg tablet (brands include Levonelle® 1500® / Upostelle®)
Legal status	POM – Prescription only medicine
Dose	1.5mg (1 tablet) Patients taking liver enzyme-inducing drugs within the last 4 weeks: 3mg (2 tablets) Patients weighing over 70kg or with a BMI > 26kg/m^2: 3mg (2 tablets) The tablets to be taken as a single dose as soon as possible after UPSI. Medication should be encouraged to be taken on the premises. If the patient is breastfeeding the dose should be delayed until just after the next feed. If vomiting occurs within 3 hours of taking levonorgestrel, a replacement dose should be given and the patient may need to be referred to a doctor to co-prescribe an anti-emetic.
Route	Oral
Frequency of administration	Single treatment dose.
Adverse Reactions	Adverse reactions considered as being at least possibly related to levonorgestrel have been categorised by frequency. Frequencies are reported as: Very common (≥1/10) Common (≥1/100 to <1/10) *Very common* Nausea Headache Bleeding not related to menses Low abdominal pain Fatigue *Common* Delay of menses more than 7 days Irregular bleeding or spotting Dizziness Diarrhoea Vomiting Breast tenderness This is not a fully comprehensive list of side effects of this medicine; refer to the Summary of Product Characteristics for more information.
Reporting procedure of Adverse	Any serious adverse reaction to levonorgestrel should be documented in the patient's PMR. The GP should also be informed. The adverse reaction should be reported to the MHRA by the yellow

Reactions	card scheme (http://www.yellowcard.gov.uk).
***Drug interactions**	**Liver enzyme inducing medication** may reduce the effectiveness of levonorgestrel. An increased dose (see dose section) is therefore recommended if any of the following are being taken or within the last 4 weeks: o Anti-retrovirals – most regimes o Barbiturates o Bosentan o Carbamazepine o Eslicarbazepine o Griseofulvin o Modafinil o Oxcarbazepine o Perampanel o Phenytoin o Primidone o Rifabutin o Rifampicin o Rufinamide o St Johns Wort o Topiramate **Anti-diabetic medication**. Levonorgestrel may affect the requirements for oral anti-diabetic medication and insulin. **Warfarin**. Levonorgestrel may alter the effect of warfarin. *This list is not exhaustive and all prescribed and over the counter medications being taken by the patient must be checked in the current edition of the British National Formulary (BNF) Appendix 1: Interactions or in the on-line BNF.
Patient advice / Follow up treatment	Discussion regarding option of post-coital Cu-IUD fitting, include: o Mode of action – the Cu-IUD's main effects are on the endometrial lining, sperm mobility and the passage of the ovum in the fallopian tube; o Timing – the Cu-IUD may be fitted up to 5 days after unprotected intercourse or up to 5 days after the earliest likely date of ovulation (whichever is later); o Efficacy – if fitted within 5 days after UPSI or ovulation, the pregnancy rate is extremely low, reported as an overall pregnancy rate of <0.1%; o Possible side effects – menstrual bleeding may be heavier and / or more prolonged; o Effects on foetus – no evidence of harm to the foetus NB. If patient wishes to have a Cu-IUD fitted levonorgestrel should still be given as patient may not actually attend for fitting of IUCD. Discuss STIs, recommend and offer chlamydia test **Explain to patient** • This is an emergency option and should be considered a "one-off"; a regular method of contraception is recommended. • Emergency contraception only gives protection for the current risk; discuss use of condoms or other contraception for the rest of

	cycle. • Discussion of ongoing contraception, in particular long acting reversible contraception (LARC). They should be advised that they can start suitable hormonal contraception immediately, but that they must use condoms reliably or abstain from sex until contraception becomes effective. • Mode of action – levonorgestrel is thought to work mainly by delaying ovulation; it is considered ineffective if taken after ovulation has occurred. • Efficacy – studies have reported the overall pregnancy rate amongst women taking LNG-EC within 72 hours of UPSI to be 0.6–2.6%. The closer the levonorgestrel is taken to the UPSI the more effective it is. • Possible side effects – see adverse reactions. • Action to take if vomiting occurs within 3 hours of taking levonorgestrel. • There are no known effects on foetus if treatment fails. • That lower abdominal pain means they should seek medical attention as it could be an early sign of an ectopic pregnancy. • That their next period may be early or late. • That they need to seek medical attention in 3-4 weeks if they have an abnormal / absent period or if they are otherwise concerned as they need a pregnancy test. All clients to be given the manufacturer's patient information leaflet in the pack along with the additional patient information sheet (Appendix 2). **Additional information to give for off label use** • Explore other options • Inform the patient that the medication is being used outside its licence and why the product is not licensed for this use • Ensure the directions for taking the medication are understood, as they may contradict standard written instructions **Information to give for Missed or late Oral Contraceptive Pills (OCP)** • **Missed Progestogen Only Pills (POPs)** Emergency hormonal contraception is indicated if a pill is late or missed and there has been UPSI or barrier failure before efficacy has been re-established (i.e. 48 hours after restarting). The levonorgestrel dose replaces that day's pill. **Note**: timing of ovulation after missed pills cannot be accurately predicted; an emergency Cu-IUD is therefore only recommended up to 5 days after UPSI. • **Missed Combined Oral Contraceptive Pills (COCs) (Note: - other than Qlaira®)** • Follow the Faculty of Sexual and Reproductive Healthcare CEU guidelines for missed combined oral contraceptive pills (COCs) (see Appendix 3) • Advise condom use for 7 days until 7 consecutive pills have been taken • The levonorgestrel dose if administered should replace that day's pill.

	Additional information for women taking hypoglycaemic medication or on insulin • Levonorgestrel may affect insulin or anti-diabetic medications requirements – they may need to seek medical advice to manage their blood sugars. • Advise blood sugar monitoring in patients on insulin **Additional information for women taking warfarin** • Levonorgestrel may alter the effect of warfarin • Advise to contact their anticoagulation clinic for advice **Additional information to women who are breastfeeding** • Small amounts of active ingredients can pass into breast milk, but it is not thought to be harmful to the baby • Advise to take tablets immediately after a breast feed **Additional information for women who have had a previous ectopic pregnancy** • Patients should be followed up by Sexual Health Sheffield or by their GP within 3 weeks
Follow up arrangements	Encourage follow up with GP or the Sexual Health Sheffield to discuss; • effectiveness of treatment – carry out pregnancy test if next menstrual period is delayed by more than 1 week or is much shorter or lighter than usual • future management if the next period has not occurred • future contraception advice • sexual health and STIs • any concerns
Records	Treatment episode to be recorded on pro-forma. • All completed pro-formas should be kept in the pharmacy until the patient is 25yrs old. Claim forms should be submitted as per service specification. • Pro-formas retained in pharmacies may need to be made available to Sheffield City Council for audit purposes.
Storage	• Medication will be supplied in single dose boxes containing 1 tablet. • A dispensing label will be added to the box if the patient is to take the dose off the premises. • All packs will contain a patient information leaflet.

Authorisation for the supply of Levonorgestrel 1.5mg Tablet

Sheffield City Council PGD (Approved: March 2018 Expiry: March 2020)

Authorisation for named professionals within an individual community pharmacy	
Community Pharmacy designated lead for professional authorisation (must be a pharmacist)	Name of Pharmacy: Name of lead for this PGD: Designation: **Has responsibility to ensure that only fully competent, qualified and trained pharmacists implement this PGD.** **Agrees to maintain a current list of the names of individuals who may implement this PGD and to keep this with a pharmacy master copy of the PGD** Signature: Date:

Note to pharmacists: in signing this document, you are stating your competence in the supply of **Levonorgestrel 1.5mg tablet** and agreeing to accept professional responsibility for any supply you make. PGDs do not remove inherent professional obligations or accountability.

Pharmacists to whom this Patient Group Direction applies:

- I have read and understood this PGD 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.

Named Pharmacist	Signature	GPhC Registration Number	Date

All pharmacists: keep original copy of authorisation form and send one copy to:

Amy Buddery
Health Improvement Principal
Public Health
Sheffield City Council
Floor 7, West Wing
Moorfoot Building
Sheffield S1 4PL

Emergency Contraception Decision Tree for Young Women Aged 14-17 Years

This chart recommends first line choice of EC treatment. This summary is not intended to include all the content, inclusions and exclusions of the oral EC PGD/guideline which must be referred to and followed for all EC supplies.

At all stages consider safeguarding implications.

Abbreviations

EC = Emergency Contraception
UPA = Ulipristal acetate 30mg (ellaOne®)
LNG = Levonorgestrel 1.5mg
UPSI = unprotected sexual intercourse
Cu-IUD = copper intrauterine device
SHS = Sexual Health Sheffield

Woman presents for EC <120 hours since UPSI

No → Refer to SHS / GP

Yes

Check previous request for EC - if ≥3 episodes in 6 months refer to SHS

Accepts Cu-IUD

Offer Cu-IUD as the most effective form of EC
Can be inserted for EC within 5 days after the first UPSI in a cycle, or within 5 days of earliest estimated date of ovulation, whichever is later.

Refer for emergency Cu-IUD fitting to be carried out ASAP and continue with EC supply

Declines Cu-IUD

*Note: If previous UPSI in cycle and EC used, the same EC should be used this time. If now inappropriate refer to SHS / GP

Any previous UPSI (>120 hours) in cycle where EC was **not** taken? *

Yes → Refer to SHS / GP

No

Last UPSI <96 hours ago?

Yes

Taking enzyme inducer medication or within last 4 weeks?

Yes

No

UPSI likely to have taken place ≤5 days prior to the estimated day of ovulation?

Yes or unknown

No

BMI>26kg/m^2 or weight >70kg

Yes

No

No or unknown

Last UPSI <120 hours ago?

No → Refer to SHS / GP

Yes or unknown

NOTE: oral EC is unlikely to be effective if taken after ovulation

Reconsider Cu-IUD
Double dose LNG

UPA**
Reconsider Cu-IUD if all UPSI within 96 hours or if currently within 5 days after likely ovulation
If UPA not suitable LNG

UPA**
or
Double dose LNG

LNG

UPA**
Reconsider Cu-IUD if:

- all UPSI within 120 hours or if currently within 5 days after likely ovulation
- enzyme inducing medication
- missed pill

**Consider reduced effectiveness if a woman has previously taken a progestogen, PPI, H2 receptor antagonist or antacid.

Author: Emily Pratt, Medicines Management Pharmacist, NHS Sheffield CCG
February 2018; review March 2020

Appendix 1

Training Requirements

Professional qualification	Registered Pharmacist
Specialist qualifications, training or experience required	Specialist training in emergency contraception to include: Understanding of o The PGD o The actions of levonorgestrel o Inclusion and exclusion criteria o Dose, form, side effects and efficacy o Possible interactions with other medication o Any follow up action and the circumstances when it would be necessary o Off label indications Trained in principles of Fraser competence The EHC and Safeguarding CPPE modules should be undertaken. Self-declaration of the above via completion and return of the CPPE Self Declaration of Competence for Community Pharmacy Services – Emergency Contraception. This should be repeated every three years.
Details of continued training or education required	All pharmacists have responsibility to maintain their professional knowledge and competence and should take steps to address any deficits in this area. Any updates in relation to the provision of this service will be provided via Community Pharmacy Sheffield (CPS).

Appendix 2

PATIENT INFORMATION SHEET

PHARMACISTS NAME:

CONTACT NUMBER:

DATE OF ATTENDANCE:

DATE OF RISK:

TIME OF RISK:

EMERGENCY HORMONAL CONTRACEPTION

You have been supplied with:

Take the tablet(s) as soon as possible

If you should vomit within 3 hours of taking the tablet you should return to the Pharmacy Service to obtain a replacement tablet as soon as possible. If the Pharmacy is not open you could attend either:
- Sexual Health Sheffield Service at the Royal Hallamshire Hospital Tel 0114 226 8888
- Sheffield City Walk in Centre at Rockingham House, 75 Broad Lane, Sheffield, S1 3PB Tel 0114 241 2700
- Your own GP

You can find your nearest service by visiting http://www.sexualhealthsheffield.nhs.uk

Condoms should be used for contraceptive protection until an alternate method of contraception is effective, these can be obtained from various sources, e.g. Sexual Health Services.

If you have not had a period within 4 weeks from now or if your period is 7 days late you are advised to make an early appointment with your doctor or the clinic so that a pregnancy test can be arranged.

EMERGENCY COIL FITTING

If you would like to discuss fitting of an emergency coil (copper intrauterine device) at Sexual Health Sheffield, please telephone 0114 226 8888 as soon as you can.

CONTINUING CONTRACEPTION

Levonorgestrel or ulipristal acetate work well when regular contraception fails or in an emergency but are not reliable as an ongoing measure and they offer no further protection in the current menstrual cycle. There are other contraceptive measures that are very reliable and easy to use for example - implants or contraceptive pills. Sexual Health Sheffield or your GP can provide information on these.

Appendix 3

CEU Guidelines for Missed Combined Oral Contraceptive Pills (COCs) (Note:- <u>other</u> than Qlaira®)

Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit Statement
Missed Pills Recommendations May 2011 http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf

If one pill has been missed (more than 24 hours and up to 48 hours late)

Continuing contraceptive cover

- The missed pill should be taken as soon as it is remembered
- The remaining pills should be continued at the usual time

Minimising the risk of pregnancy

Emergency contraception (EC) is not usually required, but may need to be considered if pills have been missed earlier in the packet or in the last week of the previous packet. The EHC replaces that day's COC.

If two or more pills have been missed (more than 48 hours late)

Continuing contraceptive cover

- The most recent pill should be taken as soon as possible
- The remaining pills should be continued at the usual time
- Condoms should be used or sex avoided until seven consecutive active pills have been taken. This advice may be overcautious in the second and third weeks, but the advice is a backup in the event that further pills are missed

Minimising the risk of pregnancy

If pills are missed in the first week (Pills 1–7)	If pills are missed in the second week (Pills 8-14)	If pills are missed in the third week (Pills 15-21)
EHC should be considered if unprotected sex occurred in the pill-free interval or in the first week of pill-taking. The EHC replaces that day's COC.	No indication for EHC if the pills in the preceding 7 days have been taken consistently and correctly (assuming the pills thereafter are taken correctly and additional contraceptive precautions are used).	OMIT THE PILL-FREE INTERVAL by finishing the pills in the current pack (or discarding any placebo tablets) and starting a new pack the next day.