PATIENT GROUP DIRECTION (PGD) FOR Community Pharmacy Supply of EMERGENCY HORMONAL ORAL CONTRACEPTION

Levonorgestrel 1.5mg	POM

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition

Indication	To provide emergency contraception (EC) to women following unprotected sexual intercourse (UPSI), compromised use of regular method of contraception (see FSRH Guidance) or failure of a barrier method of contraception. Ideally an emergency IUD (Cu-IUD) should be inserted at first presentation, the patient should be advised that this is the most reliable method of emergency contraception however where this is not possible or in the instance of patient refusal oral EC should be given in the interim, (in case the IUD cannot be inserted or the women changes her mind) and the woman advised to attend for insertion at the earliest appropriate time. **The decision-making algorithm in the FSRH Emergency Contraception Guidance 2017 should be referred to, to support choices between Ulipristal EC (UPA-EC) and Levonorgestrel EC (LNG-EC) .**
Inclusion criteria	Women* presenting within ideally within 12 hours but up to 72 hours of intercourse at risk of pregnancy due to: ○ Unprotected sexual intercourse ○ Failure of barrier method of contraception ○ Reduced efficacy of contraceptive method. ○ Refer to current BNF or Faculty of Sexual & Reproductive Healthcare . Examples include: ○ Missed taking the contraceptive pill ○ Severe diarrhoea and vomiting which may have reduced

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oral contraceptive efficacy

- More than 98 days have elapsed since the last Medroxyprogesterone Acetate injection or 70 days since the last Norethisterone Enantate injection
- Removal, perforation, expired (see guidance for lifespan of IUD/IUT) complete or partial expulsion of Cu-IUD/ LNG-IUS
- Lapsed/broken Sub Dermal Implant (see current FSRH Guidance for lifespan of SDI)
- Vomiting within 3 hours of taking levonorgestrel emergency contraceptive pill
- Previous UPSI in same cycle and treated with levonorgestrel
- Previous UPSI within same cycle and treated with ulipristal (A further course of levonorgestrel may be supplied in the same cycle if it was taken for a previous episode of UPSI if > 5 days ago since treatment with UPA)
-

*Treatment of patients aged under 16 years must meet Fraser Guidelines.

If a patient is under 16, child protection issues **WILL** be considered

Exclusion criteria

- Less than 21 days post partum
- Lack of valid consent or Fraser competency
- Unprotected sexual intercourse occurred more than 72 hours ago
- Severe intestinal malabsorption syndrome ie active Crohn's disease
- Acute Porphyria

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- Actual or suspected pregnancy (confirm with pregnancy test)
- Hypersensitivity to levonorgestrel or any of the excipients (see product insert)
- Patients with rare hereditary problems of galactose intolerance, the Lapp lacatase deficiency or glucose-galactose malabsorption should not take this medicine as this product contains lactose
- Severe arterial disease
- Past ectopic pregnancy
- Previous history of salpingitis
- Unexplained or unusual vaginal bleeding
- Severe hepatic (liver) disease
- History of breast cancer or current breast cancer
- Patients taking ciclosporin as levonorgestrel may increase the risk of ciclosporin toxicity
- Patients taking St John's Wort
- Any previous experience of severe clinical problems with hormonal contraception apart from nausea
- Women presenting <5 days after termination, ectopic pregnancy, or uterine evacuation for gestational trophoblastic disease.

ALWAYS check concurrent medication for interactions before supply under this PGD. Refer to appendix 1 of the current BNF and product SPC.

Management of excluded patients

- Refer to GP/Sexual Health service as soon as possible and ideally within 72 hours of UPSI
- Ulipristal acetate (EllaOne®) tablets can be given up to 5 days (120 hours) of UPSI

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	• A Cu-IUD can be inserted up to 5 days after the expected date of ovulation in a regular cycle or up to 5 days (120 hours) after a single episode of unprotected sex at any point in her cycle • Document reasons for exclusion • All advice should be documented in the patient's notes as should patient's refusal to consent and any action taken • 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 • If under 13 years of age the local safeguarding procedure must be followed and the relevant authorities involved, whether or not a supply of levonorgestrel is given ○ Supply of levonorgestrel can be made under this PGD if clinically appropriate and the individual is Fraser competent
Cautions/Need for further advice/Action to be taken	• Women using enzyme inducing drugs, including herbal remedies containing St John's Wort (see Special Considerations/ Additional information section and appendix 1 BNF), should be advised that a Cu-IUD is the preferred option for emergency contraception. ○ Women who decline this method or who are not eligible for Cu-IUD can take 3mg (ie a double dose) of levonorgestrel as soon as possible but within 72 hours of UPSI. However women should be informed that the effectiveness of this regimen is unknown, but thought to reduce the efficacy of the medication • Repeated administration can be given within a menstrual cycle but advice should be given that the menstrual cycle may be disrupted, and that repeated courses of EHC are

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	not the best form of contraception, and do not provide any further cover through the cycle, so a more suitable alternative should be sourced • Women can be offered levonorgestrel if they have had UPSI earlier in the same cycle as well as within the last 5 days, as evidence suggests that levonorgestrel does not disrupt an existing pregnancy and is not associated with fetal abnormality**.** • Women who present for emergency contraception should be advised to consider long-term methods of contraception and that no method is effective after ovulation. • If a woman requires EC because of non-compliance with hormonal contraception, the possibility must be considered that residual circulating progestogen from the recently-taken contraception could theoretically reduce the effectiveness of UPA-EC. Pharmacists may choose to offer LNG-EC in this situation with immediate quick start/recommencing of a suitable ongoing contraceptive method.
Action if patient declines	• Advise on alternative sources of treatment such as Cu-IUD • Refer to Sexual Health service or GP if appropriate • Document in patient's record reason for refusal and advice given • If refused Cu-IUD record in patient record • 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

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Drug Details	
Name, form and strength of medicine	Levonorgestrel 1.5mg tablet
Legal status and Licensing Information	POM The following uses are outside the terms of the Product Licence: • Under 16 years of age • Use more than once in a cycle • increased dose of levonorgestrel in patients taking enzyme inducing medicines • increased dose of levonorgestrel in patients with body-weight over 70 kg or BMI over 26 kg/m2
Route/Method	Oral The Pharmacist will supervise the adminstration of the tablet (unless there is special circumstances and the patient is unable to attend in person).

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Dosage	One tablet of 1.5 mg / 1500mcg taken as a single dose taken as soon as possible, preferably within 12 hours and no later than 72 hours after UPSI. If the woman vomits within 3 hours of taking Levonorgestrel 1.5mg a replacement dose should be given as long as the replacement dose is within 72 hrs after UPSI. For women taking enzyme-inducing drugs or weight >70kg/ BMI > 26 kg/m2 (see Special Considerations/ Additional information section or Appendix 1 BNF) a single 3mg dose (two tablets) should be taken **(off-licence use)** following Faculty of Sexual & Reproductive Health (FSRH) guideline on Emergency Contraception May 2017
Frequency of dose	Once within 72 hours of UPSI
Duration of treatment	Once within 72 hours of UPSI
Maximum or minimum treatment period	A maximum of 2 courses can by given in any single menstrual cycle **(off licence use).**
Quantity to supply	**One tablet of 1.5 mg / 1500mcg taken as a single dose.** For women taking enzyme-inducing drugs, or weight >70kg/BMI >26 kg/m2 a single 3mg dose (two tablets) can be taken **(off-licence use)** following Faculty of Sexual & Reproductive Health (FSRH) guideline on Emergency Contraception May 2017. **However women should be informed that the effectiveness**

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of this regimen is unknown and patients should be advised that a Cu-IUD is the most preferred option.

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Common side effects

Mostly well tolerated.

Very common side-effects (>1/10):

- bleeding not related to menses
- nausea
- headache
- low abdominal pain
- fatigue.

Common side-effects (>1/100):

- vomiting
- diarrhoea
- breast tenderness
- headache
- dizziness
- delayed period
- irregular bleeding and spotting.

Any suspected adverse drug reaction, whether to a drug supplied or administered to the patient by the practitioner or to a drug already taken by the patient, must be reported to a doctor immediately or as appropriate.

Suspected adverse reactions to *any* therapeutic agent should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme.

The public can report adverse effects directly to the MHRA via the Yellow Card Scheme and should be encouraged to do so.

Yellow cards can be obtained from pharmacies, GP surgeries,

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	via Freephone 0808 100 3352 or online at www.yellowcard.gov.uk
Supporting facilities	The following supporting facilities must be available: • A confidential consultation area
Records	The following must all be recorded: • An assessment of patient need in relation to the intervention including patient history, date of last menstrual period, possibility of pregnancy, inclusion criteria and criteria for referral • An assessment of patients' understanding of the treatment (if under 16 years) • Record any actions taken if a child protection issue is identified or suspected • Date and time of supply • Product name, batch number and expiry date • GPhC number and name of pharmacist who supplied medication • Patient name, address and date of birth • Number of hours after UPSI levonorgestrel supplied • Patient consent or refusal • If excluded, a record of referral

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- Information given to the patient
- Details of any other prescribed or non prescribed medication taken including herbal remedies
- Advice given if patient is excluded or declines treatment
- Details of any adverse drug reactions (ADRs) and actions taken
- Record 'off-license' use as stipulated in the PGD under Inclusion criteria and patient consent to 'off-license' use
- Follow up arrangements if appropriate

Special Considerations/ Additional information

- Emergency contraception is an occasional method. It should in no instance replace a regular contraceptive method
- Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with Levonorgestrel 1.5mg following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded
- Ectopic pregnancies may occur following use, as

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- Levonorgestrel 1.5mg is more effective at preventing intrauterine rather than tubal pregnancies. Particularly at risk are women with a history of ectopic pregnancy, fallopian tube surgery, history of salpingitis or pelvic inflammatory disease
- Women who become pregnant after EHC use should seek medical follow up to exclude the above
- Consider referral to a prescriber for consideration of quick start contraception
- The effectiveness of progesterone-only preparations may be considerably reduced by interaction with drugs that induce liver enzyme activity such as:
- Atazanavir
- Barbiturates (Phenobarbital/phenobarbitone, amobarbital/amylobarbitone, butobarbital/butobarbitone, secobarbital/quinalbarbitone)
- Aprepitant
- Bosetan
- Fosphenytoin
- Perampanel
- Carbamazepine
- Oxcarbazepine
- Eslicarbazepine
- Efavirenz
- Felbamate
- Griseofulvin
- Lopinavir
- Modafinil
- Nelfinavir
- Fosamprenavir

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- Fosaprepitant
- Amprenavir
- Lopinavir
- Lumacaftor
- Nevirapine
- Phenytoin
- Primidone
- Phenylbutazone
- Rifabutin and rifampicin
- Rufinamide
- Ritonavir
- Saquinavir
- Topiramate
- St John's Wort

- **Note: Rifampicin and rifabutin are such potent enzyme-inducing drugs that an alternative method of contraception is always recommended. Even if a course lasts for less than 7 days the additional contraceptive precautions should be continued for at least 4 weeks after stopping treatment**
- Aprepitant can reduce the efficacy of hormonal contraceptives during and for 28 days after administration of the drug. Alternative non-hormonal back-up methods of contraception should be used during treatment with aprepitant and for 2 months following the last dose
- **Broad spectrum antibiotics (antibacterials that do not induce liver enzymes)**, should not in theory, impair the effectiveness of the progesterone-only preparations,

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and a large study of the Committee on Safety of Medicines yellow cards showed no evidence of such an interaction.

Off-License Use

Medicines can be used outside their licensing indication and be given under a PGD if such use is exceptional, justified by best practice and the status of the product is clearly described. In addition, you should be satisfied that you have sufficient information to administer the drug safely and, wherever possible, that there is acceptable evidence for the use of that product for the intended indication (NMC 2004).
Where a medicine is supplied outside product license, the patient should be informed and this must be documented in the patient's record together with confirmation that the patient has consented to an unlicensed treatment being used.

Advice to Patients

- Inform women about the different methods of emergency contraception (EC) with regard to efficacy, adverse effects, interactions, medical eligibility and need for additional contraceptive precautions
- Discuss the option of a Cu-IUD and arrange appointment at Sexual Health clinic or GP surgery where emergency IUD can be fitted
- Advise patient that levonorgestrel is not the most effective EHC as FRSH now clearly state that ulipristal most effective.
    - A Cu- IUD is the most effective form of emergency contraception. All eligible women presenting

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between 0 and 120 hours of UPSI (or within 5 days of expected ovulation) should be offered a Cu-IUD
    - Women with a BMI >26 kg/m2 or weight >70 kg should be informed that levonorgestrel may be less effective and should be strongly advised to consider a Cu-IUD however levonorgestrel can be still be provided, as a double dose (3mg) if BMI>26/weight >70kg.
    - The effectiveness of EC with levonorgestrel may be reduced around the time of ovulation, increasing the risk of pregnancy and should be advised to consider a Cu-IUD
    - If Cu-IUD is not accepted supply levonorgestrel as clinically appropriate
- After taking levonorgestrel, 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**.** Oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception for refrain from sex to avoid further risk of pregnancy. Supply condoms if required
    - EHC can delay ovulation and move the fertile period on by 5 days, increasing the risk of pregnancy later into the cycle
- Advise patient of 'off-license' use of Levonorgestrel 1.5mg (as in Inclusion criteria section) under this PGD and ensure valid consent is given by patient before supply made

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- Advise that Levonorgestrel 1.5mg should be taken as soon as possible after UPSI, preferably within 12 hours and no later than 72 hours
- If vomiting occurs within 3 hours of taking the tablet that they should return promptly for further treatment or contact the Integrated Sexual Health service/GP
- Advise if the patient vomits within 3 hours of taking Levonorgestrel 1.5mg a replacement dose should be given within 72 hrs of UPSI
- Ensure the patient has a patient information leaflet
- Discuss efficacy rates and in particular that Levonorgestrel is not 100% effective.
- Discuss increased efficacy of Cu-IUD especially if mid-cycle as insertion of an Cu-IUD is more effective than Levonorgestrel 1.5mg for emergency contraception
- Advise that menstrual cycle timing may be disrupted
- Advise the patient to carry out a pregnancy test if period is more than 5 days late or period is abnormal in any way. If under 19 years of age present to Integrated Sexual Health services for a pregnancy test.
- Advise to seek medical advice if there is any lower abdominal pain as this could signify an ectopic pregnancy
- Discuss safe sex. The use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases. Advise where condoms are available if required and signpost where appropriate
- Discuss need for reliable contraception for the remainder of cycle and advise on reliable ongoing, long-term contraception (including LARCs)

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- Patients taking oral contraception should be advised: To continue taking oral contraceptives as usual
- Missed Pill advice: If taking the combined oral contraceptive pill and has 7 or less pills left in packet the patient should be advised that at the end of the packet to omit the pill free interval and continue with next pack without a break
- Following use of Levonorgestrel 1.5mg: Use an additional barrier method of contraception for 7 days if taking combined oral contraceptive and for 2 days if taking other progesterone only contraceptives and 9 days for Qlaira
- Levonorgestrel is secreted into breast milk. Potential exposure of an infant can be reduced if breastfeeding women take the tablet immediately after breastfeeding and avoid nursing for 8 hours after administration. Available limited evidence indicates that levonorgestrel has no adverse effects on breastfeeding or on their infants.
- Levonorgestrel may affect the requirement for oral anti-diabetics and insulin, so closer monitoring is advised.

Staff Characteristics

Qualifications	Pharmacist currently registered with the General Pharmaceutical Council of Great Britain
Additional	• Pharmacist with appropriate underpinning knowledge to

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requirements

competently undertake the clinical assessment of patients leading to treatment according to the indications listed in this PGD

- This PGD can only be provided by a pharmacist who is competent to provide the service and has signed and completed Schedule 3 in the associated Emergency Contraception Contract 2020 and having read the FSRH Guidance on Emergency Contraception 2017. https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/
- Each individual pharmacist is responsible for ensuring that they maintain competence and undertake appropriate training for all services that they provide.
- Each pharmacy contractor is responsible for ensuring that the pharmacists who provide the Spectrum commissioned EHC service working under this PGD are competent to do so and that competency for each pharmacist can be demonstrated if asked to provide evidence of that competency.
- Pharmacists must ensure that the pharmacy where they are providing the service has signed and is working to the terms of a Locally Enhanced Service Agreement before any supplies are made.
- By signing up to this PGD the pharmacist accepts personal responsibility for working under it, understands the legal implications of doing so and works within the scope of the PGD.

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	• **It is the responsibility of the pharmacist to ensure they have appropriate knowledge of the medicine prior to its supply.**
Continued training requirements	• The pharmacist must have signed the pharmacy copy of the PGD, (see authorisation, page 23) and ensure that the PGD is retained in the pharmacy • The pharmacist must be aware of any changes to recommendations for the medicines listed • It is the responsibility of the individual to keep up-to-date with Continuing Professional Development.

Referral Arrangements and Audit Trail

Referral arrangements	Refer to Integrated Sexual Health Service or GP as appropriate
Audit trail	• Patient's name, address, date of birth and consent given • Diagnosis • Drug supplied and dose • Date of treatment • Advice given to patient (including side effects) • Name and GPHC number of pharmacist who supplied the medication • Details of any adverse drug reaction and actions taken • Follow-up arrangements

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References

- West and South Yorkshire and Bassetlaw Commissioning Support Unit Patient Group Direction for Community Pharmacy Supply of Emergency Hormonal Oral Contraception: Levonorgestrel Expires 31st March 2017
- Summary of Product Characteristics for Levonorgestrel 1.5mg tablets https://www.medicines.org.uk/emc/medicine/32205 accessed 17/07/20
- BNF online version https://www.medicinescomplete.com/mc/bnf/current/
- Faculty of Sexual & Reproductive Healthcare Clinical Guidance - Drug Interactions with Hormonal Contraception January 2017 (last updated January 2019) Faculty of Sexual & Reproductive Healthcare Clinical Guidance. - Progesterone only pills. March 2015, Amended April 2019
- Faculty of Sexual & Reproductive Healthcare Service Standards for Record Keeping (July 2019)
- Faculty of Sexual & Reproductive Health (FSRH) guideline on Emergency Contraception March 2017 (Amended December 2017)

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Authorisation

PGD Development Group - Spectrum Community Health	
Lead Doctor	Name: Dr Joanne Thomas Position: Associate Medical Director Signature: Joanne Thomas Date: 04/08/2020
Lead Nurse	Name: Belinda Loftus Position: Cluster Manager - Sexual Health Signature: Belinda Loftus Date: 04/08/2020
Lead Pharmacist	Name: Christine Rowlands Position: Chief Pharmacist Signature: Date:04/08/2020

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

Commissioner authorisation of Spectrum Community Health Patient Group Direction

The authorising body is signing that Spectrum Community Health has followed the local processes and governance arrangements and not for the clinical content of the PGD. For use by Pharmacies in the Wakefield District sub-contract by Spectrum Community Health Wakefield Integrated Sexual Health Service.

Title of PGD: **Levonorgestrel 1.5mg for Community Pharmacy supply**

Levonorgestrel 1.5mg	**POM**

Date approved: July 2020 PGD Reference number: 20\40
Review date: February 2023
Expiry date: June 2023

Version 4.0

Commissioner Signature	Job Title	Date
AG Hawley	Director of Public Health	5 October 2020

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Individual Authorisation

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Professionals CANNOT delegate tasks under this PGD to anyone else.

If this is an updated or replacement PGD, please ensure that all previous versions are withdrawn from use with immediate effect and that the current version is used.

Each professional should be provided with an individual copy of the clinical content of the PGD and a photocopy of this page showing their authorisation should be forwarded to their line manager to be kept in their personal file.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

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Individual Authorisation	
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 professionals 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:

Pharmacists 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 within my Code or Professional Conduct

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Named Pharmacist	**Signature**	**GPhC Number**	**Date**