Patient Group Direction of the supply of Levonorgestrel Emergency Hormonal Contraception (Levonorgestrel 1.5mg tablet – LNG)

PGD Working Group

Name and role	Job title and organisation
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Patient Group Direction for the supply of Levonorgestrel Emergency Hormonal Contraception (Levonorgestrel 1.5mg tablet – LNG)

Clinical condition

Situation / condition	• Request for Emergency Hormonal Contraception (EHC)
Inclusion criteria	1. People who could get pregnant, this includes cisgender women, transgender men and non-binary (assigned female at birth) people who have not had hysterectomy or bilateral oophorectomy who within the previous 72 hours have: • Had unprotected sexual intercourse (UPSI) on any day of a natural cycle or • if their regular contraception has been compromised or has been used incorrectly **And** have been counselled in both oral and intrauterine methods with an explanation that a Cu-IUD is the most effective form of emergency contraception • **And** have chosen this oral method when a Cu-IUD cannot be fitted immediately or has been refused 2. People who could get pregnant, this includes cisgender women, transgender men and non-binary (assigned female at birth) people who have not had hysterectomy or bilateral oophorectomy who within 72 to 96 hours previously, have: • Had unprotected intercourse, or experienced failure of contraceptive method • **And** are unsuitable for or decline ulipristal acetate (EllaOne) (see FSRH algorithm) • **And** have declined a referral for an emergency intrauterine device despite being aware that the IUD would be a more effective method of preventing pregnancy; and that the efficacy of LNG is reduced at 72 to 96 hours post intercourse **(N.B. This is an unlicensed use of levonorgestrel but is supported by the FSRH. Persons should be made aware that this is based on limited evidence of efficacy.)**

	3. Levonorgestrel (LNG) may be used more than once in a cycle if clinically indicated. **(Unlicensed use but considered a good practice point by FSRH).** LNG is the recommended option if the repeat supply is within 120 hours of a previous dose of LNG. Persons should be made aware that this based on clinical judgement and not on research evidence. 4. Persons who weigh >70kg or who have a BMI>26 meeting these criteria to be offered a double dose (3mg) **(Unlicensed use but considered a good practice point by FSRH).** 5. Persons who are taking enzyme inducing medication (including St John's Wort) or have done within 28 days and who meet these criteria to be offered a double dose (3mg). **(Unlicensed use but considered a good practice point by FSRH).**
Exclusion criteria	• Girls under 16 years of age not considered competent under the Fraser ruling • Unprotected intercourse or failure of contraception more than 96 hours previously in current cycle • Request for EHC within 120 hours of taking ulipristal acetate (UPA) due to a second episode of UPSI – a second supply of UPA should be considered • Suspected pregnancy where menstrual bleeding is overdue or was abnormal • Unexplained vaginal bleeding and/or lower abdominal pain • Client aware of any medical reason where progestogen-only oral contraceptives including LNG, should not be taken • Current severe liver disease • Current breast cancer • Acute active porphyria • Allergy to any component of levonorgestrel 1.5mg tablet • Replacement supply due to vomiting. Refer to GP/contraception clinic as anti-emetic may be required • Severe malabsorption states, or medical condition that might affect

	levonorgestrel absorption e.g. Active Crohn's disease • Current gestational trophoblastic neoplasia with abnormal hCG • Concomitant therapy with ciclosporin. Progestogens inhibit metabolism of ciclosporin, leading to increased risk of toxicity • Any other medical condition where the practitioner is unclear about issuing
Action if patient excluded	• Advise immediate referral to GP or Contraception Clinic. An effort must be made to contact the GP or Clinic by telephone to confirm patient can be seen • If attending within 120 hours since first episode of unprotected sexual intercourse or earliest calculated ovulation, advise that fitting of an emergency IUD may be appropriate. Referral to GP or Contraception Clinic is required with that time frame. • Advise STI screen after 14 days and give GUM clinic information • Advise on going need for contraception and use of condoms. Discuss the choices available and signpost to further information

Staff Characteristics

Qualifications required	• Registered Community Pharmacist • All Nurses with a valid Nursing and Midwifery Council (NMC) registration working within the NMC *code-standards of Conduct (2018)*
Additional requirements	Specifically for Community Pharmacists: • Initial attendance for new pharmacists within 6 months at a specific training event organised by Public Health Cornwall Council (PHCC). All pharmacists must complete this training every 3 years • Completion of Declaration of Competency and thereafter annually • Satisfactory Disclosure and Barring Service (DBS) check every three years • Completion of the following CPPE learning programmes (and associated updates and assessments) prior to

	attendance at the PHCC organised training event: 1. Completion of EHC e-learning and e-assessment 2. Completion of the Contraception e-learning and e-assessment 3. Completion of the Safeguarding and e-assessment (2022) – Level 2 Completion of previous versions of these programmes is acceptable as long as the pharmacists' CPD portfolio reflects recent updates with assessment completed every three years to include updates and changes. • The pharmacist must sign and retain a copy of the PGD and complete the enrolment criteria on PharmOutcomes, and been subsequently authorised to provide the service by Public Health Cornwall Council in an accredited pharmacy Or if a pharmacist is accredited to provide levonorgestrel under a PGD in another Clinical Commissioning Group (CCG) within England: • The pharmacist must contact the Prescribing Team at NHS Cornwall and Isles of Scilly ICB via email at ciosicb.prescribing@nhs.net and gain authorisation use this PGD. The pharmacist will be required to explain and provide evidence of the training undertaken that enabled him to work under the PGD in the foreign CCG. The prescribing team will assess if the training undertaken matches that required under this PGD • The pharmacist must read and familiarise themselves with the PGD and sign and retain a copy, enrol on PharmOutcomes and contact PHContracts@cornwall.gov.uk giving notification of the accredited pharmacy(s) within which they will provide service • If the pharmacist is going to remain working in Cornwall for 6 months or more then they must attend a specific training event organised by PHCC within 6 months and every 3 years thereafter, along with completion of CPPE requirements Specifically for Registered Nurses:

	1. Completion of appropriate training to ensure specific competency to be arranged by employing organisation adopting this PGD. Training must be approved by PHCC contraceptive and clinical governance lead 2. Evidence of supportive training in contraception, sexual health, safeguarding children and where appropriate vulnerable adults to be approved by the Clinical lead 3. Completion of self-assessment of competency form every 12 months 4. Satisfactory DBS check
Continuing education and training requirements	• Regular updated in the field of contraception and sexual health, and child protection • Completion of any relevant additional training specified by NHS Cornwall and Isles of Scilly ICB

Medicinal Product Information

Medicinal product	• Levonorgestrel 1.5mg tablet
Legal status	• POM
Licensed use	• Levonorgestrel 1.5mg tab is not recommended in children; very limited data is available in females under 16 years of age. However, if sexual intercourse has taken place, emergency contraception may be appropriate
Dose	• One tablet should be taken as soon as possible preferably within 12 hours and no later than 72 hours after unprotected sexual intercourse (licensed use). The earlier the dose is given, the greater the efficacy • Persons who weigh >70kg or who have a BMI>26 meeting these criteria to be offered a double dose (3mg) (Unlicensed use but considered a good practice point by FSRH). • **For patients taking enzyme inducing drugs or who have stopped taking them within the last 28 days** including, but not limited to: barbiturates (including primidone), phenytoin, rifabutin, carbamazepine, eslicarbazepine, oxcarbazepine, perampanel, rufinamide, topiramate, griseofulvin, rifampicin, most protease inhibitors and antiretroviral agents

	(excluding NRTIs), St Johns Wort (See current BNF for all interactions). Two tablets should be taken as a single dose as soon as possible preferably within 12 hours and no later than 72 hours after unprotected sexual intercourse (unlicensed use). NB This is an unlicensed use of levonorgestrel but is supported by the FSRH. Women should be made aware that this is based on clinical judgement and not on research evidence. **Reinforce the use of a copper IUD as the EC method of choice in this instance for maximum benefit.** • A dose taken between 72 and 96 hours will have reduced efficacy, and is unlicensed **(See Inclusion Criteria)**
Method of administration	• Oral preferably taken on the premises
Procedure for second dose in current cycle	• In order to assess whether a previous dose may have been effective in preventing pregnancy, details of that supply must be given by the patient. Details must include: 1. Which emergency hormonal contraceptive used; levonorgestrel or ulipristal acetate 2. The circumstances of the need for EHC (this may help in the discussion on future contraception needs) 3. How long after unprotected sexual intercourse EHC was taken (this will determine the potential success of the EHC dose) 4. Any adverse effects experienced by the patient • One EHC dose. The earlier the dose is taken the greater the efficacy. It is therefore useful if the client takes the tablet(s) on the premises • Advise the need for pregnancy testing as described below
General nature of supply	• Where possible encourage patient to take the tablet(s) on the premises in your presence • If the patient declines to do so, agree a time when the dose will be taken • If medication is to be taken away, the product must be fully labelled as dispensed medicine together with the phrase "Supplied under Patient Group Direction"
Advice to be given	• Discuss mode of action of post coital contraception • Discuss failure rate and compare to CU-IUD

	• If vomiting occurs within three hours of taken the tablet(s) then contact GP or Contraception Clinic to obtain replacement tablet without delay • EHC may delay the subsequent bleed. A pregnancy test should be done if the next period is more than a week late, or if the bleed is different in any way • Identify the patient information leaflet within the levonorgestrel pack • Counsel patient on possible side effects (nausea and vomiting, breast tenderness, headache, dizziness, fatigue, bleeding pattern may be temporarily disturbed) • Advise the patient that they must contact the GP promptly if any lower abdominal pain occurs • If patient attend because of a missed pill, confirm that she knows how to proceed with remaining regime (see latest BNF or FSRH publication for missed pill guidance) • Stress the need for appropriate ongoing contraception • Provide information on local contraception services (Appendix A) • Provide information on sexually transmitted infections (STI) and local GUM services (Appendix A) • Advise STI screen (including chlamydia test), particularly if recent change of sexual partner or two or more partners in the last twelve months
Advice to be given to the patient if a second supply is made within a current cycle (*unlicensed*)	• Even if a previous dose of EHC was taken, there is still a possibility of pregnancy; however, a subsequent dose of LNG will not have any detrimental effect on the foetus • A subsequent dose of LNG taken after sexual intercourse will not prevent any pregnancy from a previous encounter in the same cycle • Most pregnancy tests will not accurately show a positive result until a minimum of 14 and potentially 23 days after exposure. Therefore, a pregnancy test should be carried out within 7 days of the first day of the missed period, or no less than three weeks of taking the EHC dose if a hormonal method has been quick-started • Advice should be given as to future contraception choices, and the patient

	should be referred to a service provider as considered appropriate
Follow up treatment	• Advise patient to attend a Contraception Clinic or their GP is their next period is more than five days late or is unusual in any way, or for those taking combined hormonal contraception, if there is no bleed in the pill-free interval
Record keeping	• Electronic or paper records with information to support the clinical decision made and advice given
Audit Trail	• PMR entry (The product must be fully labelled and state 'Supplied under Patient Group Direction' if it is to be taken off the premises) • Provisions and interaction recorded through PharmOutcomes
Reporting procedures for adverse reactions	• All severe reactions (including minor reactions in children under 18 years) to levonorgestrel are to be reported to the MHRA through the Yellow Card System
References-general	• **Current British National Formulary**: London: British Medical Association and Royal Pharmaceutical Society of Great Britain • **Cornwall Joint Formulary:** https://www.eclipsesolutions.org/Cornwall/ • **NMC (2008) The Code – Standard of conduct, performance and ethics for nurses and midwives care.** • NMC (2008) **Standards for medicine management**
Specific guidance	• Summary of Product Characteristics – Levonelle 1500 • Summary of Product Characteristics – EllaOne • Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Clinical Effectiveness Unit: Emergency Contraception, March 2017 (UpdatedDecember 2020) • Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Clinical Effectiveness Unit: Drug Interactions with Hormonal Contraception, May 2022 • Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Clinical Effectiveness Unit: Quick Starting Contraception, April 2017 • Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Clinical

	Effectivness Unit: Intrauterine Contraception March 2023 • CKS Topic-Emergency Contraception http://cks.nice.org.uk/contraception-emergnecy#!topicsummary • Pillai S. (2009) Advice on Emergency Contraception **The Pharmaceutical Journal**, 282: 79-82

Management

Date of PGD	2nd August, 2023
Date this PGD becomes due for review	1st August, 2026

Approved by:

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