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

Clinical condition

Situation/condition	• The supply of Emergency Hormonal Contraception (EHC)
Inclusion criteria	1. Women aged 25 years and under who within the previous 72 hours have: • had unprotected sexual intercourse, or experienced failure of a contraceptive method, • **and** have been counselled in both oral and intrauterine methods with an explanation that an IUD is the most effective form of emergency contraception • **and** have chosen the oral method as an IUD cannot be fitted immediately or has been refused 2. Women aged 25 years and under who, within 72 to 96 hours previously, have • had unprotected intercourse, or experienced failure of contraceptive method • **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 EHC is significantly reduced at 72 to 96 hours post intercourse • **and** are unsuitable for or decline a referral for ulipristal acetate (Ellaone) through the GP (unsuitability includes previous use of levonorgestrel or ulipristal acetate in current cycle, those with severe asthma insufficiently controlled by oral glucocorticoid, concurrent or recent treatment with an enzyme inducing drug or concurrent treatment with medicinal products that increase gastric pH – see SPC for full details). **(N.B. This is an unlicensed use of levonorgestrel but is supported by the FSRH. Women should be made aware that this is based on limited evidence of efficacy.)** 3. Unless contraindicated, women aged 25 years and under presenting within 96 hours of unprotected intercourse who wish to be referred for emergency IUD should still be encouraged to take an EHC dose. 4. Levonorgestrel may be used more than once in a cycle if clinically indicated. (**Unlicensed use but considered a good practice point by FSRH).** Women should be made aware that this is based on clinical judgement and not on research evidence. NB levonorgestrel and ulipristal acetate cannot be used within the same cycle. If client is under 16 years of age, assess competency according

	to the Fraser Ruling.
Exclusion criteria	• Women aged 26 years and over. • 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 not addressed by emergency contraception. • Unprotected intercourse or failure of contraception in current cycle addressed by ulipristal acetate. • Suspected pregnancy where menstrual bleeding is overdue or was abnormal. • Unexplained vaginal bleeding and/or lower abdominal pain. • Client aware of any medical reason why progestogen-only oral contraceptives including EHC, should not be taken. • Current severe liver disease. • Current breast cancer. • Acute active porphyria. • Allergy to any component of levonorgestrel. • 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 likely ovulation, advise that fitting of an emergency IUD may be appropriate. Immediate referral to GP or Contraception Clinic is required. • Advise STI screen and give GUM clinic information • Advise on going need for contraception and use of condoms. Discuss the various contraceptive choices

	where appropriate.

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* (2008)
Additional requirements	Specifically for Community Pharmacists: • Attendance every two years at a specific training event organised by Public Health Cornwall Council (PHCC). • Completion of self-assessment of competency form and thereafter annually. • Satisfactory Disclosure and Barring Service (DBS) check. • Completion of the following CPPE learning programmes (and associated updates) prior to attendance at the PHCC organised training event: 1. Emergency contraception (CPPE 2012; e learning) 2. Safeguarding children and vulnerable adults (CPPE 2012; e learning) 3. Contraception (CPPE 2013; open learning) Completion of previous versions of these programmes is acceptable as long as the pharmacist's CPD portfolio reflects recent updates. • The Pharmacist must have submitted the PGD signing sheet with copies of the PHCC training session certificate, and CPPE certificates, and been subsequently authorised to provide the service by the PHCC 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 Kernow CCG on 01726 627953 and gain authorisation to 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 submit the PGD signing sheet to PHCC. • 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 2 years thereafter. Specifically for Registered Nurses: 3. Attendance every two years at a specific training event

	organised by the PHCC. 4. Completion of self-assessment of competency form every 12 months. 5. Satisfactory DBS check. • Appropriate Family Planning and Child Protection training. • The nurse must have submitted the PGD signing sheet with copies of the PHCC training session certificate, and appropriate family planning and child protection certificates to PHCC.
Continuing education and training requirements	• Regular updates in the field of family planning, child protection, reproductive health care (including postcoital contraception) and sexual health. • Completion of any relevant additional training specified by the NHS Kernow.

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. • **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 levonorgerstrel 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

	significantly 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 was used; levonorgestrel or ulipristal acetate. If ulipristal acetate has been used in current cycle levonorgestrel cannot be supplied and patient needs to be referred for an IUD. 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 a 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 • If vomiting occurs within three hours of taking the tablet(s), then contact GP or Contraception Clinic to obtain replacement tablet without delay. • EHC may disrupt the menstrual cycle and there is a chance that pregnancy could still occur. 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, headaches, dizziness, fatigue. Bleeding pattern may be temporarily disturbed). • Advise the patient that she must contact the GP promptly if any lower abdominal pain occurs. • If patient attends because of a missed pill, confirm that she knows how to proceed with remaining pill regime (see

	latest BNF or FSRH publication for missed pill guidance). • Stress the need to use reliable barrier method of contraception or abstain from sexual intercourse until next menstrual period. • Advise the need for appropriate on going contraception. • Provide information on local family planning 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 EHC will not have any detrimental effect on the foetus. • A subsequent dose of EHC 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, and certainly within three weeks of taking the EHC dose. • 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 Contraception Clinic or their GP if their next period is more than five days late or is unusual in any way, or for those on the pill, if there is no bleed in the pill-free interval.
Record keeping	• Completion of PMR • Completion of PGD checklist • Completion of consent form and Fraser Ruling declaration if appropriate, counter-signed by patient. • (Community Pharmacists) Completion of the audit claim form after each consultation clearly stating the name of the supplying pharmacist.
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) • A copy of the completed checklist and consent form to be made and retained on the premises for 2 years. • (Community Pharmacists) All invoices for supplies made to be sent to invoices@cornwall.gov.uk by the 5th of the month following the month of the supply. Invoices received for supplies made more than three months previously will

	not be reimbursed
Reporting procedure 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 - Standards 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, August 2011 (Updated January 2012) • Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Clinical Effectiveness Unit: Drug Interactions with Hormonal Contraception, January 2011 (Updated January 2012) • Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Clinical Effectiveness Unit: Quick Starting Contraception, September 2010 • Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Clinical Effectiveness Unit Statement: Update on newer antiepileptic and retroviral drugs and interactions with hormonal contraceptives, March 2013 (amended August 2013) • CKS Topic-Emergency Contraception http://cks.nice.org.uk/contraception-emergency#!topicsummary • Pillai S. (2009) Advice on Emergency Contraception. **The Pharmaceutical Journal,** 282: 79- 82

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Management

Date of PGD	1st April 2015
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