Patient Group Direction of the supply of Ulipristal Acetate for use as Emergency Hormonal Contraception (Ulipristal Acetate 30mg tablet – UPA)

PGD Working Group

Name and role	Job title and organisation
Dr Sarah Gray	Clinical Governance Lead for Sexual Health and Contraception, Public Health, Cornwall Council
Marco Motta	Head of Prescribing and Medicines Optimisation NHS Cornwall and the Isles of Scilly ICB
Dr Chris Reid	Interim Chief Medical Officer, NHS Cornwall and Isles of Scilly ICB Cornwall and the Isles of Scilly ICB
Rachel Wigglesworth	Director of Public Health, Cornwall Council

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Clinical condition

Situation/condition	• The supply of 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 of reproductive age who within the previous 120 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 cannot be fitted immediately or has been refused – see FSRH algorithm 2. Unless contraindicated, presenting within 120 hours of unprotected intercourse who wish to be referred for emergency IUD should still be encouraged to take UPA 3. Ulipristal acetate (UPA) may be used more than once in a cycle if clinically indicated. There is no evidence that it will present a risk to a pregnancy arising as a failure of previous use. UPA is the recommended option if the repeat supply is within 120 hours of the previous dose. If client is under 16 years of age, assess competency according to the Fraser Ruling.
Exclusion criteria	• Girls under 16 years of age not considered competent under Fraser Ruling • Unprotected intercourse or failure of contraception more than 120 hours previously in current cycle not addressed by emergency contraception • Request for EHC within 120 hours of taking levonorgestrel (LNG) due to a second episode of UPSI – a second supply of LNG should be considered • Suspected pregnancy where menstrual bleeding is overdue or was abnormal • Less than 21 days after childbirth • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).

	• Unexplained vaginal bleeding and/or lower abdominal pain • Current use of enzyme inducing drugs (including St John's wort) or having taken within 28 days • Use of progestogen containing hormonal contraception within previous 7 days • Severe malabsorption states, or medical condition that might affect absorption e.g., Active Crohn's disease • Client aware of any medical reason why UPA should not be taken • 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 the patient that fitting of an emergency IUD is more effective. If accepted referral to GP or contraception clinic is required within this timeframe • 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 The Code - Professional standards of practice • and behaviour for nurses, midwives • and nursing *(2018)*
Additional requirements	**Specifically for Community Pharmacists:** • Pharmacists are required to complete the CPPE learning modules as detailed below. Attendance at a locally delivered EHC workshop (virtual and free of charge) when entering the scheme is <u>strongly recommended</u> and thereafter encouraged every three (3) years from a quality improvement perspective.

	• 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): 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 4. The pharmacist must have read the relevant PGD and confirm this as part of their enrolment on Pharmoutcomes. 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 Integrated care board 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/her to work under the PGD in the foreign ICB. 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.

	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	• Ulipristal Acetate 30mg tablet
Legal status	• POM
Dose	• One tablet should be taken as soon as possible preferably within 12 hours and no later than 120 hours after unprotected sexual intercourse (licensed use)
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 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 on 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

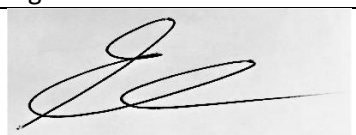
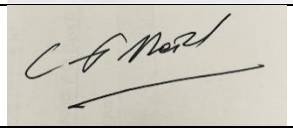
	• If medication is to be taken away, the product must be fully labelled as a dispensed medicine together with the phrase "Supplied under Patient Group Direction"
Advice to be given	• Discuss mode of action of post coital contraception • Discuss failure rate and compare to CU-IUD • If vomiting occurs within three hours of taking the tablet(s) to return for a further supply. • Advise not to breast feed for a week (she can express and discard the milk to maintain lactation) • 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 UPA pack • Counsel patient on possible side effects • Advise the patient that she must contact the GP promptly if any lower abdominal pain occurs • Advise of the need for appropriate on-going contraction. If wishing to quick start hormonal contraception explain need for 5-day delay with additional barrier contraception according to method chosen • 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 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 UPA will not have any detrimental effect on the foetus • A subsequent dose of UPA 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 is contraception 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 later or is unusual in any way, or for those using 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 interactions recorded through PharmOutcomes
Reporting procedure for adverse reactions	• All severe reactions (including minor reactions in children under 18 years) to ulipristal acetate 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 https://www.medicines.org.uk/emc/product/8859/smpc#gref • Summary of Product Characteristics – EllaOne https://www.medicines.org.uk/emc/product/6657/smpc • Faculty of Sexual and Reproductive Healthcare Clinical Guidance, Clinical Effectiveness Unit: Emergency Contraception, March 2017 (Updated December 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 Effectiveness Unit: Intrauterine Contraception March 2023) • CKS Topic-Emergency Contraception https://cks.nice.org.uk/contraception-emergency#!topicsummary • Pillai S. (2009) Advice on Emergency Contraception. **The Pharmaceutical Journal**, 282: 79-82 • Contraceptive services for under 25s, NICE guidelines [PH51] (2014) https://www.nice.org.uk/guidance/ph51 • Service Standards for Sexual and Reproductive Healthcare (FSRH) https://www.fsrh.org/Public/Public/Standards-and-Guidance/clinical-standards.aspx • Emergency Contraception CEU Guidance – (FSRH 2017, amended July 2023) https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-guideline-emergency-contraception03dec2020-amendedjuly2023-11jul.pdf • UK National Guideline on Safer Sex Advice (BASHH & BHIVA 2012) https://www.bashh.org/_userfiles/pages/files/resources/safer_sex_2012.pdf • Reducing sexually transmitted infections, NICE guideline (NG221) (NICE 2022) https://www.nice.org.uk/guidance/ng221 • GMC guidance 0-18 (2018) https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/0-18-years

Management

Date of PGD	8th January 2025
Date this PGD becomes due for review	31st March 2028

Approved by:

	Name	Signature
Head of Prescribing NHS Cornwall and Isles of Scilly ICB	Marco Motta	
Interim Chief Medical Officer, NHS Cornwall and Isles of Scilly ICB	Dr Chris Reid	
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