Luton

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

within Community Pharmacies in Luton

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1.0 April 2020	New template developed by SPS PGD development group
Version 1.3 March 2022	Review and adoption of template by Luton Borough Council
Version 2.0 November 2024	Review of PGD in line with SPS PGD development group update Oct 2023

PGD Development Group: This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in October 2022.	
Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

PGD authorisation - The clinical content has been approved by:

Name	Job title and organisation	Signature	Date
Carolynne Allan	Director of Pharmacy Services at ECG Healthcare. GPhC 2038268	CAllan (Nov 18, 2024 10:34 GMT)	18/11/2024
Richard Lyon	Medical Director at ECG Healthcare. GMC 6097348	Prof R Lyon (Nov 15, 2024 10:29 GMT)	15/11/2024
Sally Cartwright	Director of Public Health. Luton Borough Council.		18/11/2024

Training and competency of registered healthcare professionals

Qualifications and professional registration	Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.

Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. This training is specified in the current Service Specification Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults. All accredited pharmacists are responsible for maintaining the clinical knowledge appropriate to their practice by attending relevant study days, courses and by keeping abreast of evidence based practice related to sexual health.
Competency assessment	Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence for emergency contraception. Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD. If any training needs are identified these should be addressed and further training provided as required. Organisational PGD and/or medication training as required by Public Health Luton.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

Clinical condition

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly.
Criteria for inclusion	Any individual presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. No contraindications to the medication. Where informed consent has been given.

Criteria for exclusion	Where informed consent is not given. Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. Individuals 16 years of age and over and assessed as lacking capacity to consent. This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours. Known pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider a pregnancy test if more than three weeks after UPSI and no normal menstrual period). Less than 21 days after childbirth. Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). Known hypersensitivity to the active ingredient or to any component of the product. See Summary of Product Characteristics Use of levonorgestrel (LNG-EC) or any other progestogen in the previous 7 days (i.e. hormonal contraception including combined oral contraception, hormone replacement therapy or use for other gynaecological indications). Concurrent use of antacids, proton-pump inhibitors or H2-receptor antagonists including any non-prescription (i.e. over the counter) products being taken. Severe asthma controlled by oral glucocorticoids. Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping such products. Acute porphyria.
Cautions including any relevant action to be taken	All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. Ulipristal acetate (UPA-EC) is ineffective if taken after ovulation. If the individual vomits within three hours from ingestion of UPA-EC, a repeat dose may be given. For Body Mass Index (BMI) >26kg/m2 or weight >70kg: Individuals should be advised that though oral EC methods may be safely used,

	a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of UPA-EC is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. Breast feeding: Advise the individual to express and discard breast milk for 7 days after UPA-EC dose. The effectiveness of UPA-EC can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs, including combined oral contraception, for 5 days after UPA-EC. UPA EC is generally not recommended in a missed pill situation. See section 'Written information and further advice to be given to individual'. If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
Action to be taken if the individual is excluded or declines treatment	Explain the reasons for exclusion to the individual, and document in the consultation record. Record the reason for decline in the consultation record. Offer suitable alternative emergency contraception, or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options.

Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet
Legal category	P
Route of administration	For oral administration

'Off label' use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off-label use in the following conditions: • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption • Severe hepatic impairment Medicines should be stored according to the conditions detailed in the product SPC. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI
Duration of treatment	A single dose is permitted under this PGD. If vomiting occurs within 3 hours of UPA-EC being taken, a repeat dose can be supplied under this PGD. Repeated doses, as separate episodes of care, can be given within the same cycle. Please note: • If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC) • If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC)
Quantity to be supplied	Appropriately labelled pack of one tablet.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org Refer also to FSRH guidance on drug interactions with hormonal contraception

Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following side effects are common with UPA-EC (but may not reflect all reported side effects). They include, nausea or vomiting, abdominal pain or discomfort, headache, dizziness, muscle pain, dysmenorrhea, pelvic pain, breast tenderness, mood changes, fatigue. The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.
Management of and reporting procedure for adverse reactions	Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk. Record all adverse drug reactions (ADRs) in the individual's medical record. Report any adverse reactions via organisation incident policy.
Written information and further advice to be provided	All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. Ensure that a patient information leaflet (PIL) is provided within the original pack. If vomiting occurs within three hours of taking the dose, the individual should return for another dose. Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. Provide advice on ongoing contraceptive methods, including how these can be accessed. For repeated episodes of UPSI within one menstrual cycle, the dose may be repeated more than once in the same menstrual cycle should the need occur. In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following UPA-EC use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for

	STIs. There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased.
Advice/follow up treatment	The individual should be advised to seek medical advice in the event of an adverse reaction. The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. Pregnancy test as required (see advice to individual above). Individuals advised how to access on-going contraception and STI screening as required.

Records	Make records of the following:
	
	• The consent of the individual and:
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ If individual over 16 years of age and not competent, record action taken
	• Name of individual, address, date of birth
	• GP contact details where appropriate
	• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight
	• Any known drug allergies
	• Name of registered health professional operating under the PGD
	• Name of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied including batch number and expiry date
	• Advice given, including advice given if excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns
	• Any referral arrangements made
	• Any supply outside the terms of the product marketing authorisation
	• Recorded that supplied via Patient Group Direction (PGD)
	
	Records should be signed and dated (or a password controlled e-record) and securely kept for a defined period in line with local policy.
	
	All records should be clear, legible and contemporaneous.

	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Key references

- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - March 2017 (Amended July 2023) FSRH Clinical Guideline: Emergency Contraception (March 2017, amended July 2023) | FSRH
- FSRH CEU Statement Response to Edelman 2022 (August 2022) FSRH CEU Statement: Response to Edelman 2022 (August 2022) | FSRH
- Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022
  FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) | FSRH
- Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines

Luton

Registered health professional authorisation sheet

Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

Valid from: 1st November 2024 **Expiry: 31st March 2027**

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it. Patient group directions 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 professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Luton Pharmacies for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager:
Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation. This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.