PATIENT GROUP DIRECTION (PGD)

Supply of ulipristal acetate 30mg tablet for emergency contraception by Community Pharmacists and Pharmacy Technicians in England working in a pharmacy registered to provide the NHS Pharmacy Contraception Service

Version 1.0

Change History	
Version and Date	**Change details**
Version 1.0 20th June 2025	PGD Approved

This Patient Group Direction (PGD) must only be used by pharmacists and pharmacy technicians who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

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Valid from: 20th June 2025
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PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	20th June 2025
Review date	September 2025
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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 November 2022.

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ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor **Claire Fuller**	National Medical Director, NHS England		20/06/2025
Senior pharmacist **David Webb**	Chief Pharmaceutical Officer, NHS England		20/06/2025
Person signing on behalf of authorising body **David Webb**	Chief Pharmaceutical Officer, NHS England		20/06/2025

1. Characteristics of staff

Qualifications and professional registration	GPhC registered pharmacist or pharmacy technician able to practise under Patient Group Directions (PGDs).
Initial training	The pharmacist or pharmacy technician authorised to operate under this PGD must have undertaken appropriate education and training and be competent to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with the specification. To deliver this service, the pharmacist or pharmacy technician should have evidence of competence in the clinical skills and knowledge covered in the CPPE and/or the NHS England e-learning for healthcare (elfh) modules listed in the **NHS Pharmacy Contraception Service specification.** The pharmacist or pharmacy technician has completed training and is up to date with service requirements for safeguarding children and vulnerable adults.
Competency assessment	• Pharmacists or pharmacy technicians operating under this PGD must have declared their competence and must be authorised by a manager within their organisation to provide the service (see **Appendix A**). • Pharmacists or pharmacy technicians operating under this PGD are encouraged to review their competency using the appropriate competency framework tools, such as the **NICE Competency framework: For health professionals using patient group directions.**
Ongoing training and competency	• Pharmacists or pharmacy technicians operating under this PGD are personally responsible for ensuring 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 undertaken as required.
The decision to supply any medication rests with the individual pharmacist or pharmacy technician who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• This PGD applies to the NHS Pharmacy Contraception Service only: To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or when 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. • If vomiting has occurred within three hours of taking oral EC.
Criteria for exclusion	• 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 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 (SPC).

	• Use of levonorgestrel emergency contraception (LNG-EC) or any other progestogen in the previous 7 days (i.e. hormonal contraception including combined oral contraception (COC), hormone replacement therapy (or use for other gynaecological indications). • Users of 30mcg Ethinylestradiol with levonorgestrel (EE/LNG) COC who miss two pills in the first week of pill taking. • 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. • Acute porphyria. • Requests for provision of oral EC in advance as a just in case option.
Cautions including any relevant action to be taken	• 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 the local safeguarding lead and follow the local safeguarding policy. • If there are reasons to believe an individual aged 16 years of age or over lacks capacity, an assessment of capacity to consent should be conducted and recorded in their notes. Particular consideration should be given to any concern of sexual assault or sexual violence in vulnerable adults. • If the individual has not yet reached menarche consider onward referral for further assessment or investigation. • 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 EC.

	• Ulipristal acetate emergency contraception (UPA-EC) is ineffective if taken after ovulation. • **If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider.** • If individual vomits within three hours from ingestion of oral EC, a repeat dose may be given. • 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 EC for them and referred accordingly if agreed. • 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 contraception has been used incorrectly or has been compromised, EC may be indicated. Refer to **FSRH EC** guidelines (4.3 - Table 1) for additional guidance.
Action to be taken if the individual is excluded or declines treatment	• If excluded, explain the reasons for exclusion to the individual and document in the clinical record. • If the individual declines the recommended EC, record the reason(s) for declining supply in the clinical record. • Offer suitable alternative EC or where required, refer the individual as soon as possible to a suitable health

	service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet
Legal category	P
Route of administration	Oral
Off label use	Best practice advice given by FSRH is used for guidance in this PGD and may vary from the 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 manufacturers' guidance. However, in the event of an inadvertent or unavoidable deviation of these conditions, the Responsible Pharmacist must be consulted. Where medicines have been assessed by a Responsible Pharmacist 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 the Responsible Pharmacist. Where a drug is recommended for off-label use 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 as a separate episode of care.
	• 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.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: **https://www.medicines.org.uk/emc** 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): • Nausea or vomiting, • Abdominal pain or discomfort, • Headache, • Dizziness, • Muscle pain (myalgia), • Dysmenorrhea, • Pelvic pain, • Breast tenderness, • Mood changes, • Fatigue. The FSRH advises that disruption to the menstrual cycle is possible following EC.
Management of and reporting procedure for adverse reactions	• Record all adverse drug reactions (ADRs) in the individual's medical record. • Pharmacists, pharmacy technicians and individual's/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme: http://yellowcard.mhra.gov.uk
Management of and reporting procedure for patient safety incidents	• The pharmacy is required to report any patient safety incidents in line with the https://www.gov.uk/government/publications/clinical-governance-approved-particulars.
Written information and further advice to be given to individual	• All methods of EC 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 EC. • Provide a patient information leaflet (PIL) with the original pack. • If vomiting occurs within three hours of taking the dose, the individual should be advised to return for another dose.

	• Explain that menstrual disturbances can occur after the use of oral EC. • Provide advice on ongoing contraceptive methods, including how these can be accessed. • 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. • Explain oral EC methods do not provide ongoing contraception. • 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 after oral EC, there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle. • 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. • Where appropriate, promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. • Advise there is no evidence of harm if someone becomes pregnant in a cycle when they had used oral EC. • Breast feeding – there is no need to avoid breastfeeding after taking a single dose of UPA-EC as per **FSRH guidance**. • Advise to consult a pharmacist, pharmacy technician, nurse or doctor before taking any new medicines or herbal products 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 the individual above). • Individuals should be advised how to access on-going contraception and STI screening as required.

Records	Record:
	
	• 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 is over 16 years of age and not competent, record action taken.
	• Name of individual, address, date of birth.
	• GP contact details where appropriate.
	• Reason for EC request: UPSI / regular contraception has been compromised / regular contraception used incorrectly / vomiting has occurred within three hours of taking oral EC.
	• Relevant past and present and sexual medical history, including medication history (to include over the counter, herbal medications, supplements and recreational drug use).
	• Results of biometrics and measurements where relevant e.g. weight, height and BMI.
	• Any known allergies and nature of reaction.
	• Name and registration number of pharmacist or pharmacy technician.
	• Name of medication supplied.
	• Date of supply.
	• Dose amount.
	• Quantity supplied.
	• 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 (off label use). • Recorded that supplied via PGD. Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with the specification. 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 the specification.

4. Key references

Key references (accessed September 2022, July 2023 and February 2025)	• NHS Pharmacy Contraception Service Specification : https://www.england.nhs.uk/long-read/nhs-pharmacy-contraception-service/ • 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) https://www.fsrh.org/Public/Documents/ceu-clinical-guidance-emergency-contraception-march-2017.aspx

	• Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/Public/Documents/ceu-clinical-guidance-drug-interactions-with-hormonal.aspx • FSRH statement regarding the taking of Ulipristal Acetate and Breastfeeding https://www.fsrh.org/Public/Documents/FSRH-statement-Ulipristal-Acetate-and-Breastfeeding.aspx • FSRH CEU Statement: Response to Recent Publication Regarding Banh, et al. (November 2020) https://www.fsrh.org/Common/Uploaded%20files/documents/fsrh-ceu-statement-upa-coc-restart-november-2020.pdf • 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

Appendix A – Registered pharmacist and pharmacy technician authorisation sheet

PGD Name/Version 1.0

Valid from: 20th June 2025 Expiry: 28th February 2026

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered Pharmacist and pharmacy technician

By signing this PGD, you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each pharmacist and pharmacy technician 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 PGD 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 pharmacist and pharmacy technician named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named pharmacists and pharmacy technicians 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 pharmacists and pharmacy technicians to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those pharmacists and pharmacy technicians authorised to work under this PGD.