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

in Accredited Warwickshire Community Pharmacies by an Accredited Pharmacist

Version Number 1.2

Change History	
Version and Date	**Change details**
Version 1 March 2020	New template
Version 1.1 June 2020	Information included to use the template in Warwickshire.
Version 1.2 July 2022	Information review as renewal is due November 2022

This Patient Group Direction (PGD) must only be used by registered professionals 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.

Subject to all the conditions and criteria below, this Patient Group Direction allows an accredited pharmacist in an accredited pharmacy to supply for the pharmacy, appropriately packaged, the named drug to patients for self-administration without the need for a prescription from a doctor. The pharmacist must have completed the specified additional training and confirm via the self-declaration of competency that they are professionally competent to operate and agree to work within this Patient Group Direction.

Valid from: November 2022
Expiry date: November 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	November 2022
Review date	July 2024
Expiry date:	November 2024

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 2019.

This section MUST REMAIN when a PGD is adopted by an organisation.

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)
Michael Nevill	Director of Nursing British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant Marie Stopes UK
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)
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Pan London PGD working group
Dr Sarah Pillai	Pan London PGD working group
Alison Crompton	Community pharmacist

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Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Samrina Bhatti	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS WARWICKSHIRE

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Cristina Ramos Chair & Director South Warwickshire GP Federation		30/08/2022
Senior pharmacist	Mahesh Mistry Deputy Director Clinical Services NHS Arden and Greater East Midlands Commissioning Support Unit		18/08/2022
Senior representative of professional group using the PGD			
Person signing on behalf of authorising body			

1. Characteristics of staff

Valid from: November 2022
Expiry date: November 2024

Qualifications and professional registration	Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation. Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC), who are working in a pharmacy contracted to NHS England (Warwickshire). Provider pharmacists to have enhanced level DBS status.
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 patients ensuring safe provision of the medicines listed in accordance with local policy Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or advised in the RCN training directory. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence for the supply of emergency contraception (see Appendix A) • They must recognize and work within the limits of their own individual competencies and scope of practice. The Pharmacist should be able to demonstrate the competencies specified in NICE's Competency Framework for Health Professionals using Patient Group Directions. • NICE Competency Framework for health professionals using patient group directions. • Delegation of responsibility is not permissible under PGD legislation. Ulipristal may only be supplied by the authorised pharmacist who has clinically assessed the patient under the guidance of this PGD.
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. • The pharmacist must maintain a regular self-assessment declaration of competency every two years or sooner if appropriate.

	• Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional 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	Provision of emergency hormonal contraception (EHC) to individuals within 120 hours of unprotected sexual intercourse (UPSI) which may include suspected failure of a contraceptive method.
objectives	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised.
Criteria for inclusion	• Any individual presenting for emergency hormonal contraception (EHC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. • No contraindications to the medication. • Informed consent given. • Patients on a regular oral contraceptive who are currently suffering from severe diarrhoea and/or vomiting, leading to reduced efficacy • Patient has received ulipristal acetate emergency contraception but has vomited within three hours of taking it (provided they are still within 120 hours of UPSI). • Ulipristal acetate is the first line oral EHC for a woman who has had UPSI 96-120 hours ago. • If the UPSI is likely to have taken place during the five days prior to the estimated day of ovulation, FSRH recommends ulipristal acetate as first line. **Special notes on age:** • You may still supply the medication if it is in the best interests of the patient. • All patients under 18 years: A risk assessment should be undertaken to determine whether the child is at risk of harm. If you have a concern, the matter should be discussed with the local safeguarding lead. • All patients under 16 years: Must be competent as assessed under the Fraser Guidelines on consent to medical treatment. • All patients under 13 years: The matter must be discussed with the local safeguarding lead. You may still supply the medication if it is in the best interests of the patient. • The pharmacist must be aware of their local safeguarding contact numbers for adults and children.

Criteria for exclusion	• Woman unable to attend in person. • Informed consent 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 or suspected 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. • Use of levonorgestrel or any other progestogen in the previous 7 days (i.e., hormonal contraception, hormone replacement therapy or use for other gynaecological indications). • Concurrent use of antacids, proton-pump inhibitors or H2-receptor antagonists. • Severe asthma (treated by oral glucocorticoid). • Breast cancer, ovarian cancer, uterine cancer and cervical cancer.Individuals using hepatic enzyme-inducing drugs i.e., anti-epileptics (e.g., carbamazepine, eslicarbazepine, oxcarbazepine, topiramate, phenobarbital, phenytoin, primidone, rufinamide); anti-TB drugs (e.g., rifampicin, rifabutin); anti-retrovirals (e.g., ritonavir efavirenz, nelfinavir, nevirapine); antidepressants (e.g., St John's Wort –a herbal preparation); others (e.g., aprepitant, modafinil,bosentan) / herbal products or within 4 weeks of stopping. • For more information on drug interaction, see the latest BNF and FSRH Drug Interactions with Hormonal Contraception.
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 is ineffective if taken after ovulation.

	• If individual vomits within three hours from ingestion, 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. The FRSH advise that oral contraception may be less reliable in women (Ulipristal PGD, Champs 2016) with malabsorption due to severe small bowel disease or resection. Women with these conditions should be encouraged to consider a Cu-IUD as the preferred method of emergency contraception. • Breast feeding – For women who are breast feeding inform them that breast feeding is not recommended for 7 days after taking ulipristal acetate. The manufacturers advise that women who are breast feeding should feed their baby immediately before taking the tablet, then pump and discard the milk for 7 days after taking the ulipristal acetate. Breast feeding can be resumed after 7 days. If the woman is unable or unwilling to comply with this advice, she is excluded from treatment with ulipristal acetate under this PGD - consider supply under levonorgestrel PGD or refer to GP or Community Sexual and Reproductive Health Clinic. • The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section 'Written information and further advice to be given to individual'. • Undiagnosed vaginal bleeding • 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. • Following termination of pregnancy, consider the date of termination as the last menstrual period.

Action to be taken if the individual is excluded or declines treatment	• Discuss and document why the client is excluded from the service. • Discuss and document why the patient has declined treatment • Advice the patient that a delay in starting treatment may affect its efficacy. • 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. • If clinically appropriate consider supply and administration of levonorgestrel (refer to levonorgestrel PGD).

3. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet.
Legal category	P (Pharmacy Medicine)
Route of administration	Oral. **Administration while the patient is present should be encouraged and supported, although this is voluntary.** If the tablet is not taken in the pharmacy, the woman should be advised to take it as soon as possible.
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. 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. • If the woman vomits within THREE hours of taking the dose, then a second pack may be issued if the woman is able to take the repeated dose within 120 hours following UPSI.

Duration of treatment	• A single dose is permitted under this PGD.
	• Repeated doses can be given within the same cycle. Please note:
	  ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal).
	  ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel).
	  ○

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
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 ulipristal acetate, however this list is inclusive of listed side effects but not exhaustive: • Nausea or vomiting. • Abdominal pain or discomfort. • Headache. • Dizziness. • Dysmenorrhea. • 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 patients/carers 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 patient's medical record. • Report any adverse reactions via organisation incident policy.
Written information and further advice to be given to individual	• 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. • 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 ulipristal acetate 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. In these circumstances' women should seek medical advice. • Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. • Provide three condoms to the client wherever appropriate.
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). • Ulipristal acetate is not intended for use during pregnancy and should not be taken by any woman suspected or known to be pregnant. Limited human data regarding pregnancy exposure to ulipristal acetate do not suggest any safety concern. However, if a woman does become pregnant, she must inform her doctor; and report to the manufacturer (HRA Pharma) online at www.hra-pregnancy-registry.com • Seek medical advice if the patient experiences severe lower abdominal pain as this could signify an ectopic pregnancy. • Individuals advised how to access on-going contraception and STI screening as required. • If the patient wishes to resume hormonal contraception, they should do so **AFTER 5 days**. Patient should be advised to abstain from sex or use a condom during these 5 days because no other hormonal contraception can be used during this period. When restarting oral contraception after this “gap” (i.e., on day 6), additional barrier method must be used for the requisite number of days. • Breastfeeding is not recommended for 7 days after taking

	ulipristal acetate. During this time, it is recommended to express and discard the breast milk in order to stimulate lactation. • Advise not to drive or operate machinery if affected by dizziness.

Records	Record:
	
	• The valid informed 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.
	  ○ A "Fraser Ruling Assessment of Competency" form must be completed for all women under 16 years of age.
	• 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 medication allergies.
	• Name of registered health professional operating under the PGD.
	• Name of medication supplied.
	• Date of supply.
	• Dose supplied.
	• Quantity supplied.
	• Brand, batch number, 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 administered/supplied via Patient Group Direction (PGD).
	• GPhC number and name of pharmacist who administered or supplied the medication and provided the consultation.
	
	Records should be signed and dated (or a password-controlled e-records) 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.

4. Key references

Key references (accessed July 2022)	• 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 - December 2020 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ • 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 health professional authorisation sheet

Ulipristal acetate Valid from: November 2022 Expiry: November 2024

Version 1.2

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

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.

A copy of each person's Declaration of Competency has been submitted to Warwickshire County Council via CSW-Jets(Intend). Checks will be undertaken by WCC to ensure up to date documents are available to view to enable payment against activity.

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 Warwickshire County Council for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**
Helen Earp	Sexual Health Commissioner Warwickshire County Council		??/??/22

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.