PATIENT GROUP DIRECTION (PGD)

Supply and/or administration of ulipristal acetate 30mg tablet

By registered pharmacists for

Emergency Hormonal Contraception In Community Pharmacy

Version Control

This document is only valid on the day it was printed. The most recent and in date final version of the PGD must be used.

The current version of this document can be found on Pharmoutcomes and the LPC website here

Version	Date	Author	Change description
Version 1.0	March 2024	Shola Olowosale	New template

Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

The authorising body accepts governance responsibility for the appropriate use of the PGD.

Shropshire Council and Telford and Wrekin Council authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Sexual health services provided by community pharmacies commissioned by Shropshire Council and Telford and Wrekin Council
Limitation to authorisation
The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of their self-declaration and sign up to the current PGD

Authorisation

This document requires authorisation by the following individuals:

Management			
PGD Author	Shola Olowosale Clinical Pharmacist NHS Shropshire Telford and Wrekin Integrated Care Board		
Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Rachel Robinson Statutory Director of Public Health	Shropshire Council		22/03/2024
Liz Noakes Statutory Director of Public Health	Telford and Wrekin Council		22/03/2024
Arabinda Kundu Consultant/Clinical Lead in Sexual Health	Midlands Partnership Foundation Trust		22/03/2024
Elizabeth Walker Deputy Director Medicines Management	NHS Shropshire Telford and Wrekin Integrated Care Board		20/03/2024

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.

1. Characteristics of staff

Qualifications and professional registration	▪ Pharmacist with current General Pharmaceutical Council registration. ▪ Work in a Community Pharmacy within Shropshire Council and Telford and Wrekin Council ▪ Pharmacist is required to have suitable indemnity insurance.
Initial training	▪ Has undertaken training in the use of PGDs ▪ Has undertaken training which enables the pharmacist to make a clinical assessment to establish the need and supply of treatment according to this PGD as detailed in the service specification. ▪ Has satisfied the competencies and completed the self-declaration form appropriate to this PGD, as detailed in the CPPE and NHS Health Education England *Declaration of Competence for pharmacy services – Emergency Contraception with the use of a Patient Group Direction* document https://www.cppe.ac.uk/gateway/ehc ▪ Is competent in the assessment of the individuals using Fraser guidelines and safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	▪ Individuals operating under this PGD must complete the self-declaration form appropriate to this PGD, as detailed in the CPPE and NHS Health Education England *Declaration of Competence for pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* ▪ 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 andcompetency	▪ The pharmacist should be aware of any change to the recommendation for the medicine listed. ▪ Must be able to show regular update in the field of family planning and reproductive health care including emergency contraception. ▪ Must assess and maintain their own competence every three years on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for pharmacy services – Emergency Contraception with the use of a Patient Group Direction* document. ▪ It is the responsibility of the pharmacist to keep up to date with continuing professional development ▪ It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. ▪ Attendance at a local training event(s) approved by Shropshire Council or Telford and Wrekin Council is recommended where these are organised, but this is not a prerequisite for delivering this service

The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

2. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which thisPGD applies	A patient requesting oral emergency contraception who presents within 120 hours (5 days) of unprotected sexual intercourse (UPSI) or potential contraception failure
Criteria for inclusion Use BNF/BNFC/SPC. Takeinto account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI	Women with spontaneous menstrual cycles presenting within 120hours (5 days) of UPSI or potential contraception failure (e.g., condom failure, severe vomiting/diarrhoea whilst on oral hormonal contraception, and who: ▪ Have been given information regarding the other methods available for EC (see Advice to be given to the patient or carer) and provided with information on services that can provide them but decides not to access them. (If a woman isreferred on for a copper intrauterine device (Cu-IUD), ulipristal acetate EC should be given at the time of referral incase the Cu-IUD cannot be inserted, or the woman changes her mind.) ▪ Understand the risks, benefits, and side effects of treatment with ulipristal acetate. ▪ Meet Fraser guidelines, if under 16 years of age. ***Note children under 13 years of age must be notified to the local Safeguarding Team; however, this should not prevent treatment if considered necessary under this PGD.*** ▪ Are competent to consent to treatment. ▪ Has reached the menarche ▪ Must attend in person for supply of medication to be Given

Criteria for exclusion	▪ 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. ▪ UPSI more than 120 hours (5 days) ago ▪ Known pregnancy (Suspected pregnancy should be excluded using a pregnancy test). ▪ Less than 21 days after childbirth. ▪ Less than 5 days after miscarriage, abortion, topic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). ▪ Use of hormonal contraception, levonorgestrel (LNG-EC) or any progestogen within the previous 7 days ▪ Concurrent use of antacids, proton-pump inhibitors or H_2-receptorantagonists 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 ▪ Allergy / known product ingredients
Cautions including anyrelevant 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 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. 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 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.
Supply to young persons	▪ If a young person (aged <16 years) requests Emergency Contraception, then they must be assessed for competency. If they are deemed as being 'Fraser Competent' then a supply can be made, but this must be documented in the records. ▪ Pharmacists must use their professional judgement when considering 'Safeguarding' issues related to sexual activity in young persons. ▪ If a child under 13 years requests Emergency Contraception, and there is a reasonable concern that sexual activity has taken place, the pharmacist should always contact: **Family Connect Telford - 01952 385385 or 01952676500(Out of Hours)** **Shropshire Family Information Service- 01743254400** ▪ There must always be a presumption that the case will be referred to the Children's Social Care Services in the area where the child lives. A record of the referral should be maintained in the pharmacy. ▪ The pharmacy may also adopt: **Regional Child Protection Procedures for West Mildands** ▪ If you think a child or young person is in immediate danger telephone **999**
Action to be taken if thepatient is excluded	▪ If the individual falls into the above Exclusion Criteria, UPA-EC cannot be issued. ▪ Explain reason for exclusion and record within PharmOutcomes ▪ If the individual is under 13 years of age, the Pharmacist should follow the local safeguarding procedures as outlined in the 'Supply to young person's section' ▪ If the individual is currently breastfeeding and is unwilling to suspend breastfeeding for 1 week, consider a supply of LNG-EC via PGD if clinically appropriate. ▪ If the individual is hypersensitive to UPA-EC, refer to their GP or Sexual Health Clinic ▪ If the individual is excluded for any other reason under this PGD, consider making a supply via the LNG-EC PGD if clinically appropriate, or refer to their GP or Sexual

	Health Clinic.
Action to be taken if thepatient or carer declinestreatment	▪ Inform patient/carer re risks of not receiving treatment compared to the benefits. ▪ Refer to a doctor or to the nearest available contraceptive clinic as appropriate. ▪ Advice given to individuals who require a referral must be recorded within PharmOutcomes

3. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30 mg tablet
Legal category	P
Route / method of administration	Oral
Indicate any off-label use (if relevant)	Not applicable Check product SPC to identify off label usage as this can vary between manufacturers.
Dose and frequency of administration	▪ One tablet to be taken as a single dose as soon as possible and no later than 120 hours (5 days) after UPSI. ▪ If vomiting occurs within three hours of taking, another dose should be taken immediately, but this must fall within the 120 hours (5 days) since UPSI occurred.
Duration of treatment	Single episode of treatment which may be repeated in the same cycle if appropriate.
Quantity to be supplied	Single dose of ulipristal acetate 30 mg. Patients should be observed taking the medication unless they are breast feeding, when they can be allowed to take away for later consumption, if necessary, but this must occur within the 120-hour (5day) window and breast milk should be expressed and discarded for 7days after taking ulipristal acetate.
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from theelectronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	▪ UPA interferes with progestogen containing medication ▪ If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction see Appendix 1 of BNF (https://www.medicinescomplete.com/mc/) or the Summary of Product Characteristics

	(http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF) or refer to *Clinical Guidance: Drug Interactions with Hormonal Contraception* (FSRH, January 2019) or www.hiv-druginteractions.co.uk In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given.
Identification & management of adverse reactions	**Side Effects** **Common** / **Uncommon** Influenza Appetite disorders Mood disorders / Emotional disorderAnxiety Insomnia Hyperactivity disorderLibido changes Headache / Somnolence Dizziness / Migraine Visual disturbance Nausea* Abdominal Pain* Abdominal discomfort Vomiting* / Diarrhoea Dry mouth Dyspepsia Flatulence Acne Skin lesions Pruritis Myalgia Back Pain Dysmenorrhea Pelvic Pain Breast tenderness / Menorrhagia Vaginal discharge Menstrual disorder Metrorrhagia Vaginitis Hot flush Premenstrual Syndrome Fatigue / Chills Malaise Pyrexia *Symptom which could also be related to an undiagnosed pregnancy (or related complications) * Bleeding patterns may be temporarily disturbed, but most women will have theirnext menstrual period within 7 days of the expected time. ** If the next menstrual period is more than 5 days overdue, pregnancy should be excluded. If pregnancy occurs after treatment with ulipristal acetate, the possibility ofan ectopic pregnancy should be considered. Severe abdominal pain may be an indication of ectopic pregnancy.

	For a full adverse effects profile, refer to the Summary of Product Characteristics (SPC – www.medicines.org.uk) or the most current edition of the British National Formulary (BNF – www.bnf.org
Management of and reporting procedure for adverse reactions	In the event of any adverse reaction: ▪ Record the adverse reaction in the patient consultation note ▪ Inform the patient's GP if the patient consents to this If appropriate report the adverse reaction under the Yellow Card scheme (Forms can be found at the back of the BNF or completed online; http://yellowcard.mhra.gov.uk)
Written information to be given to patient or carer	The patient/carer should be given or directed to the following written information if appropriate: ▪ The product specific patient information sheet supplied with the medicine A copy of the Family Planning Association (FPA) leaflet 'Your guide to emergency contraception' (http://www.fpa.org.uk/resources/downloads)
Patient advice / follow up treatment	The patient/carer should be given the following information verbally if appropriate and requested ▪ Advise women that the Cu-IUD is the most effective method ofEC. ▪ Advise women that UPA-EC has been demonstrated to bemore effective than LNG-EC. ▪ EC providers should advise women that the available evidencesuggests that oral EC administered after ovulation is ineffective. ▪ Effectiveness of method is dependent on length of time fromUPSI / potential contraceptive failure to treatment. ▪ Beneficial effects, side effect and risks should be discussed. ▪ Advise women that after oral EC there is a pregnancy risk ifthere is further UPSI and ovulation occurs later in the samecycle. ▪ How to take the pill correctly, preferably as an immediate dosein the pharmacy. ▪ Breast feeding mothers may be allowed to take away with them to allow them to feed their child before taking. This should only occur if it fits within the allowed time limits. Theyexpress and discard for 7 days after taking ulpristal acetate ▪ If vomiting occurs within three hours of taking, a repeat dose isrequired, but must be given within the 120 hours (5 days) since UPSI. ▪ When to seek further medical advice ▪ To refer to Sexual Health Clinic or GP if no / light period up to three weeks after treatment. ▪ Advise women that oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or abstain from sex to avoid further risk of pregnancy. ▪ Discuss on going contraception

	▪ Discuss long-acting reversible contraception and give written information that is in line with NICE guidance, CG 30, updated July 2019. ▪ Encourage use of condoms and reinforce the safer sex message. ▪ Recommend sexually transmitted infections screening. ▪ Supply or recommend condoms as detailed in the servicespecification. ▪ Use of the product outside the terms of its license should be discussed with the patient, including the reasons why this maybe necessary. ▪ Advise where the patient will continue to use a hormonal method of contraception it should not be re-started within 5 daysof taking UPA ▪ Advise that no medication containing progesterone should bestarted within 5 days
Records	▪ In discussion with the individual, enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. ▪ Informed verbal consent should be obtained (for individuals aged under 16 years, Fraser guidelines should be followed) ▪ If UPA-EC emergency contraception is supplied then the Pharmacist asks the individual to sign only when the Pharmacist is confident that the individual understands the information she has been given. ▪ Electronic patient records and/or the completed paper proforma should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records are recommended to be kept. ▪ If the individual is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. ▪ If a safeguarding referral is made, a record of the referral must be maintained in the pharmacy

4. Key references

Key reference(accessed September 2022 and July 2023)	▪ 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/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/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ ▪ 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
Glossary	UPA-EC Ulipristal Acetate 30mg tablet LNG-EC Levonorgestrel 1500mcg tablet BNF – British National Formulary SPC – Summary of Product Characteristics PIL – Patient Information Leaflet PGD – Patient Group Direction FSRH – Faculty Sexual & Reproductive Health UKMEC – UK Medical Eligibility for Contraceptive Use

Appendix A -Supply of ulipristal acetate 30 mg for Emergency Hormonal Contraception

PGD Name/Version **Valid from:** **Expiry:**

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 youwill work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practice only within the bounds of their own competenceand professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction andthat 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 insert name of

organisation 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.