Providing NHS Services

ROCHDALE METROPOLITAN BOROUGH COUNCIL

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 of ulipristal acetate 30mg tablet by registered pharmacists as first line emergency contraception in community pharmacy within Rochdale

In order to develop the Rochdale Council ulipristal emergency contraception PGD the national template version number 2.1 was adapted locally. Details of the national template are kept as a reference (please see below).

Change History	
Version and Date	**Change details**
Version 1 March 2020	New template
Version 2.0 March 2023	Updated template (no clinical changes to expired V1)
Version 2.1	Reworded exclusion and caution sections to reflect change in guidance re combined oral contraceptive, in line with updated FSRH guidance. Updated references.
12.10.23 (amendments made locally to reflect local arrangements)	Removal of some of the 'off label' recommendations to ensure consistent approach within both Rochdale emergency contraception PGDs (ulipristal 30mg and levonorgestrel 1.5mg). Addition of the following conditions: total lactase deficiency; hereditary problems of galactose intolerance; glucose-galactose malabsorption; within the section "criteria for exclusion".
	Section 1 'Characteristics of staff' amended to reflect local requirements.
	Addition of the statement on the provision of the ulipristal during pandemic.

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PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1st March 2023
Review date	September 2025
Expiry date:	28th February 2026

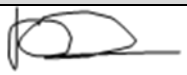
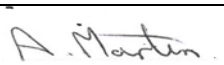
This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in October 2022.

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)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	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

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor (Clinical Lead Heywood, Middleton & Rochdale CCG)	Dr Aggy York		22.12.2023
Senior pharmacist (Strategic Medicines Optimisation Pharmacist NHS Greater Manchester)	Andrew Martin		04.12.2023
Pharmacist Representative (Director of Services, GM LPC)	Louise Gatley		17.12.2023
Authorising Signatory (Director of Public Health, Rochdale Borough Council)	Kuiama Thompson		04.01.2024

1. Characteristics of staff

Qualifications and professional registration	• Pharmacist with current General Pharmaceutical Council registration. • Pharmacist who works in a community pharmacy within Rochdale Borough Council area.
Initial training and competency assessment	The registered pharmacist authorised to operate under this PGD must: • Have successfully completed training which enables the pharmacist to make a clinical assessment in order to establish the need and supply the treatment according to this PGD as detailed in the service specification. • Have successfully completed eLfH PGD e-learning programme. • Have successfully completed locally required relevant contraception and emergency contraception courses accredited by CPPE. • Have 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 Service with the use of a Patient Group Direction document** (https://www.cppe.ac.uk/services/declaration-of-competence#navTop). • Be assessed as competent (see Appendix A). • Have successfully completed https://www.cppe.ac.uk/programmes/l/safegrding_elfh-e-04 locally required training (including updates) in safeguarding children and vulnerable adults, level 2 accredited by CPPE. • Have successfully completed locally required training in sexual health accredited by CPPE. • Be competent in the assessment of the individuals using Fraser guidelines.
Continued training and competency	Pharmacists 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. • 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 on the medicine supplied under this PGD in line with the requirements contained within the **Declaration of Competence for pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction** document. • Are responsible for keeping up-to-date with continuing professional development. • Are responsible for maintaining their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed.

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

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.

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

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. There are two emergency contraception (EC) PGDs used within the Rochdale Council. First line EC is ulipristal 30mg and second line EC is levonorgestrel 1.5mg.
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. • Informed consent given. • An individual has been provided with information that insertion of 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 however decides not to access this service (see section 'Advice to be given to the patient or carer') • An individual has been provided with information regarding Cu-IUD and it is appropriate and acceptable. This patient can be given ulipristal EC at the time of referral to appropriate health service, in case the Cu-IUD cannot be inserted or the woman changes her mind. • Must attend in person for supply of medication to be given. **NB. In the event of a pandemic pharmacists may use their professional judgement on how they provide emergency hormonal contraception e.g. via remote telephone consultation. This is provided they take steps to minimise patient risk and be mindful of potential for abuse with due regard to safeguarding. Any provision and use of professional judgement must give due consideration to the latest advice given by the General Pharmaceutical Council and Royal Pharmaceutical Society.** Supplies made utilising this temporary adjustment should be recorded as such.
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. • 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. • Use of levonorgestrel 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 H_2-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. • Total lactase deficiency. • Hereditary problems of galactose intolerance. • Glucose-galactose malabsorption. • Severe hepatic impairment.
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. Although the use of ulipristal 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 ulipristal dose. • 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, including combined oral contraception, for 5 days after ulipristal. Ulipristal 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 reason for decline in the consultation record. • Offer suitable alternative emergency contraception (e.g. second line levonorgestrel 1500 micrograms in community pharmacy if appropriate) 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.

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 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 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.

Duration of treatment	• A single dose is permitted under this PGD.
	• If vomiting occurs within 3 hours of ulipristal 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 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. • Patients should be observed taking the medication. **NB. In the event of a pandemic, the patient does not need to be observed taking the medication. The pharmacist should seek assurance from the patient they will take the dose as soon as possible and within 120 hours of UPSI or potential contraception failure when taking away.**
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 ulipristal acetate (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 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. • 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	The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory entries as required by the service specification and this PGD. The required information to be recorded is: • The consent of the individual and o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines. If not, competent record action taken. o 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 medication allergies • Name of registered pharmacist operating under the PGD • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied including batch number and expiry date in line with local procedures • 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) **As per SPS Retention of Pharmacy Record and SPS**

	Retaining PGD documentation*:* PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 26th birthday or for 8 years after a child's death. 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 Caldicott guidance, the Data Protection Act and the General Data Protection Regulation.

4. Key references

Key references (accessed December 2019)	• 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 • Specialist Pharmacy Service, Retaining and storing pharmacy records in England, June 2023 https://www.sps.nhs.uk/articles/retaining-and-storing-pharmacy-records-in-england/ • Specialist Pharmacy Service, Retaining legal mechanism documentation, June 2021 (last updated April 2023) https://www.sps.nhs.uk/articles/retaining-legal-mechanism-documentation/

Appendix A - Registered pharmacist authorisation sheet

Supply and administration of ulipristal acetate 30mg tablet by registered pharmacists as first line emergency contraception in community pharmacy within the Rochdale Council

Draft Version 2.1 Valid from: 13/01/2024 Expiry:12/01/2026

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.

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 pharmacists named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of community pharmacy for the above named pharmacists 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.

A copy of this PGD with completed pharmacist authorisation sheet should be retained and available at the pharmacy premises as a record of those pharmacists authorised to work under this PGD.