This Patient Group Direction (PGD) must only be used by registered and accredited pharmacists working in a Community Pharmacy setting in Oxfordshire who have been named and authorised by their organisation to practice under it and have a Call-off Contract to provide it.

Emergency Hormonal Contraception (EHC) Call-off Contract sits within the Dynamic Approved Provider List (DAPL) Agreement for the Provision of Community Healthcare Service Commencement Date of 1st April 2022.

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 (EllaOne) 30mg tablet(s) for emergency contraception in Oxfordshire

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1.0 March 2020	New template
Version 2.0 March 2023	Updated template (no clinical changes to expired V1)

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.

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 (Woking Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

OXFORDSHIRE COUNTY COUNCIL AUTHORISATIONS

Role / Name	Job title and organisation	Signature	Date
Lead Author, Shakiba Habibula	Consultant in Public Health, Public Health, Oxfordshire County Council		01.03.23
Lead Clinician for Contraception Dr Julia Shefras	Consultant in Community Gynaecology and Sexual Health, Oxford University Hospital NHS Foundation Trust		03.03.23
Lead Pharmacist, Esha Gupta	Senior Clinical Pharmacist, Principal Medical LTD.		06.03.23
Representative of professional group using the PGD, David Dean	Chief Executive Officer, Local Pharmacy Committee, Pharmacy in Thames Valley		07.03.23
PGD Development Lead, Liz Benhamou	Health Improvement Practitioner, Public Health, Oxfordshire County Council		01.03.23
Person signing on behalf of authorising body, Ansaf Azhar	Director of Public Health, Oxfordshire County Council		21.03.23

1. Training and Competency of registered Community Pharmacist

Qualifications and professional registration	Currently working within a Community Pharmacy in Oxfordshire that holds a Call-off Contract within the DAPL Agreement for the Provision of Community Healthcare Service with a Commencement Date of 1st April 2022. Community Pharmacists registered with the General Pharmaceutical Council (GPhC).
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 Oxfordshire local policy. Within three months of enrolment pharmacists must complete the standards required in the Declaration of Competence for Community Pharmacy Services – Emergency Contraception, hosted by CPPE. This must be completed every two years. The healthcare professional has completed training (including updates) in safeguarding children and vulnerable adults hosted by CPPE. Prior to signing Appendix A (and as part of enrolling for the service on Pharmoutcomes), pharmacists providing the service must meet the local training requirements which are as follows: • Level 1 – Safeguarding in Oxfordshire – OSCB online safeguarding • EHC provision in Oxfordshire (available on the OSCB learning website. EHC PGD Training for Pharmacists) Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme .
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) 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 • Hold a satisfactory Enhanced Disclosure and Barring Service (DBS) check because of the one to one work with people aged under 16 years renewed every three years.
Ongoing training and	• Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with

competency	the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training completed as required. • Ongoing competency and training needs should be assessed as part of regular review of all staff working under PGDs. • Organisational PGD and/or medication training as required by employing 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	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 and use of the first line LNG is not indicated (e.g., 9 – 120 hours). • Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Consider Ulipristal if the individual presents in the five days leading up to estimated day of ovulation • No contraindications to the medication. • Informed consent given. • If under 16, 'assessed as competent as per Fraser Guidelines'. • In exceptional circumstances, such as the COVID-19 pandemic, where a remote consultation has to take place, the FSRH CEU recommends that assessment of requirement for EC is prioritised so that it can be made as soon as possible after UPSI. See https://www.fsrh.org/documents/fsrh-ceu-clinical-advice-to support-provision-of-effective/
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 (LNG-EC) 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 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
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. • Inform individuals that they can contact their GP or the Oxfordshire Sexual Health Service (OSHS) (www.sexualhealthoxfordshire.nhs.uk/ 01865 231231) to organise this, or as good practice the Pharmacist could contact OSHS during the consultation if the client gives consent on 01865 231231. • If an individual chooses to contact the OSHS themselves advise them to include the following, *'requesting emergency contraception, would like to arrange for an emergency IUD (coil)'*. Their request will be prioritised. • 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 or a double dose of Levonorgestrel. • 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 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'. • Patients who have used any progestogen containing medication in the 7 days prior to presentation (whether for contraceptive purposes which includes Long Acting Reversible Contraception (LARC) and emergency contraception (levonorgestrel) or for gynaecological indications or in hormone replacement therapy (HRT). • 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. • If the individual has taken levonorgestrel in the same cycle advice is to give levonorgestrel again or if UPA-EC is the preferred option, there should be a 7 day gap between the two administrations. • In the specific situation in which an established CHC user restarts CHC after a hormone-free interval and then misses 2-7 pills in the first week of pill-taking (or makes an equivalent error with combined patch or ring use): - LNG-EC may be offered, with immediate restart of CHC and use of condoms for 7 days - If UPA-EC is preferred, it may be offered, now with immediate restart of CHC and use of condoms for 7 days (new recommendation for this specific scenario only) • Unless an individual taking UPA-EC is an established CHC user in the specific situation described above, hormonal contraception should not be started for 5 days after UPA-EC. Situations in which hormonal contraception should not be started for 5 days after UPA-EC include: - established COC users who have extended the pill-free interval or missed more than 7 pills in any week of scheduled pill taking (or established combined patch or ring users who have made an equivalent error) - New starters of any hormonal contraceptive - Established users of progestogen-only contraceptives who have used the method incorrectly. In these situations, LNG-EC with immediate quick start of hormonal contraception should be considered (no change to guidance).
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 or refer the individual as soon as possible to their GP, the OSHS www.sexualhealthoxfordshire.nhs.uk (01865 231231) or their school or college health nurse for alternative options and further information.
Arrangements for referral for medical or safeguarding advice	• Repeat attendance for EHC must be monitored and any concerns discussed with OSHS. It is good practice to encourage access to reliable contraception. Signpost to GP or OSHS or School or College Health Nurse. • If any doubt about whether to supply under this PGD, or for advice, or copper IUD referral, contact OSHS - https://www.sexualhealthoxfordshire.nhs.uk and 01865 23123. • If aged under 18, consider need for possible child

	protection process (see PharmOutcomes for guidance) or refer to the Oxfordshire Children's Safeguarding Board "reporting concerns" - https://www.oscb.org.uk/concerned-about-a-child/ • If aged over 18 and you have concerns, please refer Oxfordshire Safeguarding Adults Board - http://www.osab.co.uk • Always document the concern and outcome in the healthcare record.

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 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 Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the manufacturer must be consulted. Where drugs have been assessed by the registered healthcare professional operating under this PGD 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 registered healthcare professional operating under this PGD. 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. • 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 or a double dose of Levonorgestrel. •

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 file://rlbuht.lan/userdata/jjenkins/Downloads/drug-interactions-with-hormonal-contraception-5may2022.pdf
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 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 (advise the patient the risk of pregnancy is higher).

	• 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 any over the counter medicines.
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. • If an individual reports assault or rape, discuss need for counselling or legal action. Refer as appropriate. If the individual needs immediate support or forensics to be carried out they can self-refer to the Sexual Assault Referral Clinic (SARC) at Oxfordshire (https://www.osarcc.org.uk/) or contact the police.

Records	Record:
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken. See Safeguarding section for more information.
	  ○ 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 medication allergies
	• Name of registered health professional operating under the PGD
	• Name of medication supplied

	• Date of supply • Dose supplied • 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 • Recorded that administered/supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy using PharmOutcomes. 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 September 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 2017 (Amended March 2000) 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

Contact details:

Oxfordshire Sexual Health Service
• Telephone - 01865 231231
• https://www.sexualhealthoxfordshire.nhs.uk/

Oxfordshire County Council commissioners of DAPL and PGD for EHC
• Telephone -01865 328606
• E-mail- publichealth@oxfordshire.gov.uk

GP Practice Finder
• https://www.nhs.uk/service-search/find-a-gp

School and College Health Nurse Service
• Telephone - 07769 235 149
• E-mail - shn.oxfordshire@oxfordhealth.nhs.uk
• https://www.oxfordhealth.nhs.uk/school-health-nurses/

Appendix A – Registered Health Professional Authorisation Sheet

PGD Name/Version: PGD EllaOne April 2023

Valid from: **1st April 2023**

Expiry: **31st March 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 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.

Add details on how this information is to be retained according to organisation PGD policy.