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 community pharmacies across BNSSG

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1 March 2020	New template
Version 1.1 November 2020	Addition of acute porphyria to exclusion criteria

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

Reference Number: V1.1

Valid from: 1st March 2022

Expiry date: 28th February 2023

Date PGD template comes into effect:	1st March 2020
Review date	September 2022
Expiry date:	28th February 2023

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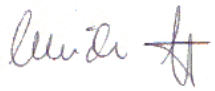
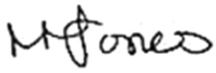
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo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

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Cindy Farmer	**Education and Training Lead for Unity Sexual Health**		22/09/2021
Debbie Campbell	**Deputy Director (Medicines Optimisation) NHS BNSSG CCG**		30/09/2021
Senior representative of professional group using the PGD	**Michelle Jones** **Senior Medicines Optimisation Pharmacist (Bristol)**		28/09/2021
Public Health Representative in Bristol City Council	**Christina Gray** **Director of Public Health for Bristol**		18/10/21
Public Health Representative in North Somerset Council	**Matt Lenny** **Director of Public Health for North Somerset**		11/10/21
Public Health Representative South Gloucestershire Council	**Prof. Sara Blackmore** **Director of Public Health for South Gloucestershire**		19/10/21

1. Characteristics of staff

Qualifications and professional registration	Registered pharmacist with current GPhC registration. Currently employed or working as a locum pharmacist in a community pharmacy in Bristol, North Somerset or South Gloucestershire
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 (including use of Fraser and Bichard guidelines as appropriate) ensuring safe provision of the medicines listed in accordance with local policy. Must have completed the following e-learning modules within the last 3 years: 1. The CPPE EHC e-learning and assessment module 2. The e-lfh Emergency Contraception and Emergency Contraception Cases e-learning modules of the e-lfh Sexual and Reproductive Healthcare course. 3. The e-lfh Raising awareness of Child Sexual Exploitation e-learning course. The healthcare professional must have completed the CPPE Safeguarding Children and adults e-learning and e-assessment module within the last 2 years.
Competency assessment	• Individuals operating under this PGD must 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
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. • 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	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 female-bodied individual up to and including 24 years, presenting for emergency contraception (EC) between 0 and up to and including 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. Ulipristal should be considered first line if UPSI is likely to have taken place during the 5 days prior to ovulation (high risk) • In exceptional circumstances, the Pharmacist may use their professional judgement to supply to vulnerable patients over 24 years if patients are not able to access emergency contraception via other routes. • To retreat a patient who has vomited within three hours of taking ulipristal emergency contraception (UPA-EC) and is still within 120 hours of UPSI • No contraindications to the medication. • Informed consent given.
Criteria for exclusion	• Informed consent not given. • The individual wishes to see a doctor or nurse • 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

Criteria for exclusion continued	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 • Unexplained or unusual menstrual bleeding • 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). Consider referral for Cu-IUD. • Concurrent use of antacids, proton-pump inhibitors or H_2-receptor antagonists. • Severe asthma controlled by oral glucocorticoids. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping. • Acute porphyria • Taking any of the interacting drugs listed in interactions
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 Unity Sexual Health Services via PharmOutcomes. • If individual vomits within three hours from ingestion, a repeat dose may be given. If the client vomits within three hours following administration of a dose but is subsequently outside of the 120-hour window for treatment a repeat dose is unlikely to be effective, and they should be referred to Unity Sexual Health Service or their GP for fitting of an IUD • 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. If the copper IUD is declined standard dose Ulipristal Acetate 30mg or levonorgestrel 2x 1500 micrograms (see levonorgestrel PGD) may be offered. • 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 for 5 days after ulipristal. See section Written information and further advice to be given to individual. • Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Therefore, Ulipristal should be considered first line if the individual presents in the five days leading up to estimated day of ovulation. • Ulipristal is ineffective if taken after ovulation • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • With all people, but particularly with the young or vulnerable, be satisfied that sexual intercourse has been consensual and is not occurring in an abusive relationship. If non-consensual sex or sexual abuse is suspected, follow local safeguarding policy. • 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. • UPA-EC can be offered to a woman if she has had UPSI earlier in the same cycle as well as within the last 5 days, as evidence suggests that UPA-EC does not disrupt an existing pregnancy and is not associated with foetal abnormality. Use of UPA-EC in pregnancy is unlicensed but is supported by FSRH and this should be explained to the patient. • If other episodes of UPSI have occurred earlier in the cycle (>120 hours ago) without using emergency contraception, Cu-IUD fitting up to day 19 (of a 28-day cycle) should be offered. • If a woman requiring oral EC for UPSI in the last 5 days has also had (or may also have had) UPSI more than 21 days ago AND has not had a normal menstrual period since the earlier UPSI the potential risk of pregnancy from

Cautions including any relevant action to be taken	the previous UPSI should be discussed. This does not exclude the use of UPA-EC for the UPSI in the last 5 days. Consider recommending a high-sensitivity urine pregnancy test (able to detect hCG levels around 20mIU/ml) before UPA-EC is taken • If a woman has already taken UPA-EC once or more in a cycle she can be offered UPA-EG again after further UPSI in the same cycle and this is supported by the FSRH as there is no evidence that UPA-EC will disrupt existing pregnancy or increase the risk of foetal abnormality if taken in very early pregnancy. Repeated administration of UPA-EC is well tolerated. • If a woman has already taken UPA-EC once or more in a cycle she can be offered UPA-EG again after further UPSI in the same cycle and this is supported by the FSRH as there is no evidence that UPA-EC will disrupt existing pregnancy or increase the risk of foetal abnormality if taken in very early pregnancy. Repeated administration of UPA-EC is well tolerated and can continue to delay ovulation for some time • Active trophoblastic disease – seek advice from Unity Sexual Health Service • Past ectopic pregnancy – seek advice from Unity Sexual Health **UPSI may have occurred as a result of any of the following:** • No contraception used • Barrier method failure e.g. slipped or split condoms, diaphragm or cap inserted incorrectly or dislodged during intercourse or found to be torn/ damaged or removed less than 6 hours after SI • Complete or partial expulsion of an intrauterine contraceptive device (IUCD) including mid-cycle IUCD removals • Prolonged oral contraceptive pill or patch or ring free interval including vomiting or diarrhoea due to medication and/or illness leading to a prolonged contraceptive pill or patch or ring free interval • Late or missed Depo-Provera® contraceptive injection. i.e. last injection administered more than 14 weeks ago • The risk of pregnancy in the fourth year of use of the implant Nexplanon® and in the sixth year of the intrauterine system Mirena® is low, and levonorgestrel may be considered in this situation • Concomitant use of drugs that induce liver enzyme activity with COCs, contraceptive patches and combined vaginal rings, POPs or progestogen only implant or within

Cautions including any relevant action to be taken	28 days of stopping them. The following list of enzyme inducing drugs is derived from the FSRH guideline 'Drug Interactions with Hormonal Contraception' 2017: ○ Antiepileptics e.g. Carbamazepine, Eslicarbazepine, Oxcarbazepine, Phenobarbital, Phenytoin, Primidone, Rufinamide, Topiramate, Perampanel, Fosphenytoin ○ Anti-infectives e.g. Rifabutin, Rifampicin, Griseofulvin ○ Anti-retroviral treatments e.g. Ritonavir, Ritonavir-boosted protease inhibitors, Efavirenz, Nevirapine. ○ Antidepressants e.g. St John's Wort (Hypericum perforatum) Bosentan, Modafinil, Aprepitant ○ Refer to the current BNF and FSRH guideline for Drug Interactions (2017) when the presenting female takes other medication.
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 Unity Sexual Health (0117 342 6900) or their GP. The PharmOutcomes consultation record can be used to automatically refer patients to Unity Sexual Health for an emergency coil subject to the patient's consent being obtained. Information about further options should also be provided.

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 Drugs 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 local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management 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 pharmacy/Medicines Management. 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 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 (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. **Anaphylaxis** Before administering any medication, the possibility of anaphylaxis must be considered and appropriate medical treatment should be available for immediate use in case of anaphylactic reactions. For further information, please see the resuscitation council guidelines. http://www.resus.org.uk/pages/glalgos.htm n http://www.resus.org.uk/pages/reaction.pdf
Written information and further advice to be given to individual **Written information and further advice to be given to individual continued**	• 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. • The pregnancy risk from a single act of intercourse is highest (between 20-30%) in the days just before and just after ovulation. Counting the first day of menstrual bleeding as day 1, the pregnancy risk is low before day 7 and after day 17 inclusive in a 28-day cycle • The possible mechanisms of action should be explained to the client as some methods may not be acceptable, depending on individual beliefs about the onset of pregnancy and abortion • UPA-EC acts by delaying ovulation for at least 5 days, until sperm from the UPSI for which EC was taken are no longer viable. UPA-EC delays ovulation even after the luteinising hormone (LH) surge whereas LNG-EC is no longer effective after the start of the LH surge. • In the late follicular phase, however, LNG-EC becomes ineffective while UPA-EC is still able to delay ovulation. • Neither UPA-EC and LNG-EC are effective post-ovulation • Inform the individual that the majority of women will go on to ovulate later in the cycle and are therefore at risk of pregnancy from subsequent UPSI. Women should be made aware of this risk regarding ongoing contraception • Ensure that a patient information leaflet (PIL) within the original pack and the FPA leaflet on emergency

	contraception are provided. • 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. Refer to Unity Sexual Health Clinic or GP if appropriate. • 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 provide information pack that contains condoms. • As part of raising awareness around sexually transmitted infections and to increase Chlamydia screening uptake, all clients presenting for UPA-EC should be informed that it does not protect against sexually transmitted infections and should be offered a Chlamydia screening kit and advised how to submit it for testing • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
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). • Advise a follow up appointment with their GP or Unity Sexual Health Service (0117 342 6900) in 3 to 4 weeks to ensure that the method has worked. • Patient should be advised to contact their GP or Unity Sexual Health Service (0117 342 6900) at any time to discuss on-going contraception. • All clients presenting for emergency contraception should be supplied with a screening kit for chlamydia. If sexually transmitted infection is suspected, refer the patient to their GP or Unity Sexual Health Service. • If clients cannot be treated under this PGD, or wish to have an emergency IUD fitted, they can be automatically referred to Unity Sexual Health via completion of the PharmOutcomes consultation record, provided patient consent is obtained.

Records	Record the supply in the patient's medication records, and the below information onto PharmOutcomes in line with the service protocol. Following the PharmOutcomes template will result in all of the required information being recorded
	
	Record:
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ If individual 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

Records continued	• 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) Note: It is strongly recommended that the client takes the dose of UPA-EC at the time of the consultation. If this is not the case, the reason why should be recorded in the clients record. 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 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 - December 2017

	https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 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

PGD Name/Version: Ulipristal EC Valid from: October 21 Expiry: 28/02/2023

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**