PATIENT GROUP DIRECTION (PGD)
Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

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

Revision History

Version	Date	Author	Change description
3.1 / 2022	May 2022	Andrew Pickard	Local update

PGD Development Group	
Name	**Job title and organisation**
Andrew Pickard (Author)	Pharmacy Advisor - NHS England & Improvement Midlands (Staffordshire and Shropshire)
Dr Tania Cork	Chief Officer, North Staffordshire and Stoke-on-Trent Local Pharmaceutical Committee
Dr Arabinda Kundu	Consultant/Clinical Director in Sexual Health, Midlands Partnership Foundation Trust
Dr Gabriel Agboado	Interim Consultant in Public Health Medicine, Stoke-on-Trent City Council
Heather Sherwin,	Contract Monitoring Officer, Stoke-on-Trent City Council
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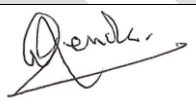
Final

Authorisation
This document requires authorisation by the following individuals:

Management			
PGD Author	Andrew Pickard, Pharmacy Advisor - NHS England & Improvement Midlands (Staffordshire and Shropshire)		
Authorisation			
Name and Designation	**Organisation**	**Signature**	**Date**
Andrea Fallon Interim Director of Public Health	Stoke-on-Trent City Council		30 May 2022
Andrew Pickard Pharmacy Advisor	NHS England & Improvement Midlands		24 May 2022
Dr Arabinda Kundu Consultant/Clinical Director in Sexual Health	Midlands Partnership Foundation Trust		24 May 2022

Specialist advice	
Dr Arabinda Kundu – Consultant / Clinical Director in Sexual Health	Midlands Partnership Foundation Trust

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

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	• Registered community pharmacists authorised by Stoke-on-Trent City Council via the EHC Service Specification to provide an Emergency Hormonal Contraception Service.
2. Competencies required to be held by staff undertaking this PGD	• Has a clear understanding of the legal requirements to operate a PGD Patient group directions (nice.org.uk) • Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself. • Has a clear understanding of the drug to be administered including side effects and contraindications. • Individuals operating under this PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.
3. Specialist qualifications, training, experience and competence considered relevant to the clinical condition treated under this PGD	• The community pharmacist must be registered with the General Pharmaceutical Council. • Completion of the current CPPE training packages on Emergency Contraception Emergency contraception : CPPE and Safeguarding Vulnerable Adults and Children Safeguarding children and adults at risk: a guide for the pharmacy team : CPPE • Completion of the CPPE learning pack – Combating CSE: An e-learning resource for healthcare professionals is required. Combatting CSE - An e-learning resource for healthcare professionals: CPPE • Attendance at a local training event(s) approved by Stoke-on-Trent City Council is recommended where these are organised, but this is not a prerequisite for delivering this service.

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR EMERGENCY HORMONAL CONTRACEPTION
Ulipristal Acetate 30mg

Clinical Details	
Indication	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or when regular contraception has been compromised or used incorrectly.
Aims	To reduce the number of unwanted pregnancies in the City of Stoke-on-Trent through the supply of appropriate emergency hormonal contraception (EHC) to specific individuals by a community pharmacist.
Inclusion Criteria	Individuals should always be advised that the 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 the individual is referred on for a Cu-IUD, oral emergency contraception should be given at the time of the referral in case the Cu-IUD cannot be fitted or the individual changes their mind. 1. Informed consent given. 2. The individual is aged 13 years or over and presents between 72 and 120 hours of having sexual intercourse without using contraception or thinks their method of contraception may have failed i.e. Unprotected sexual intercourse, barrier/condom failure, missed pills (refer to current BNF), IUD expulsion, severe diarrhoea and vomiting which may have reduced oral contraception efficacy, allowed >89 days to elapse since the last medroxyprogesterone injection. 3. Individual presents within 120 hours of unprotected sexual intercourse and the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation. As the date of ovulation usually occurs 14 days before the next expected period, individuals with longer menstrual cycles will ovulate later in the cycle. 4. If the individual has received Ulipristal Acetate 30mg (UPA-EC) under PGD, but has vomited or had severe diarrhoea within 3 hours of the dose (provided still within 120 hours of sexual intercourse) 5. The individual weighs more than 70kg or has a BMI >26kg/m^2 6. The dose may be repeated in the same menstrual cycle should the need occur (but no more than two doses in any given cycle) 7. The individual is either unable or does not wish to attend for an appointment with their GP or Sexual Health Service, and is willing to accept the limited service available through pharmacy. Individuals must always be offered information regarding access to comprehensive contraception and sexual health services available locally. 8. If the individual is excluded for any reason from receiving a supply of Levonorgestrel (LNG-EC) via PGD, a supply of UPA-EC can be considered if the requirements of this PGD are met.

	Under the terms of this PGD it is not possible to give EHC to the individual as a precautionary measure for future need against unprotected sex, neither should it be supplied via a third party.
Exclusion Criteria	1. Informed consent not given. 2. If more than **120 hours** after unprotected sexual intercourse 3. The individual is aged under 13 years - refer to "Supply to young and vulnerable adults" person section for further details. 4. Individual is aged under 16 years old and is assessed as lacking capacity to consent using the Fraser Guidelines 5. The individual is already pregnant or they think they may be pregnant 6. If the individual has used hormonal contraception in the previous 7 days. Consider Cu-IUD or LNG-EC. 7. Any individual that presents within 72 hours of UPSI and the UPSI is **not** likely to have taken place during the 5 days prior to the estimated day of ovulation. 8. Breastfeeding, unless willing to suspend breastfeeding for 1 week 9. The individuals last period was late or last period was unusual (recommend a pregnancy test) 10. Unexplained genital bleeding or unexplained amenorrhoea 11. Less than 21 days following childbirth 12. Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease **Specific medical conditions** 13. Severe asthma controlled by oral glucocorticoids 14. Diabetes mellitus with nephropathy, retinopathy, neuropathy or vascular disease 15. Current liver disease or renal disease 16. Breast cancer or previous history of breast cancer 17. Acute porphyria 18. The individual suffers from an acute severe malabsorption syndrome such as inflammatory bowel disease 19. Known hypersensitivity to the active substance Ulipristal Acetate or any of the excipients contained in the product 20. Please note, UPA-EC contains lactose. Patients with known lactose intolerance are excluded and should be referred to a GP or the Sexual Health Clinic. **Medication** Any drug interaction where concomitant use of UPA-EC is contra-indicated. This includes; • liver enzyme inducing drugs and for those individuals that have used enzyme inducing drugs within the past 4 weeks • drugs that increase gastric PH • concomitant use with ritonavir specifically.

	Please refer to current BNF https://bnf.nice.org.uk/ **and SPC for full details** https://www.medicines.org.uk/emc
Supply to young persons and vulnerable adults	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. If the young person is not deemed to be 'Fraser Competent' advice must be sought from Children's Advice and Duty Service (CHAD) on: **01782 235100**. Practitioners should discuss with CHAD the remaining need for the child to have access to Emergency Contraception to prevent pregnancy. Further guidance can be found at: Gillick competence and Fraser guidelines | NSPCC Learning Pharmacists must be aware of, and comply with the relevant safeguarding expectations from Stoke-on-Trent City Council Safeguarding Board regarding sexual activity in young people: https://www.stoke.gov.uk/info/20009/children_and_families/391/stoke-on-trent_safeguarding_children_partnership If a child under 13 years requests Emergency Contraception, and there is a reasonable concern that sexual activity has taken place, the pharmacist should contact the CHAD on **01782 235100** (Monday-Friday 8:30am-6:00pm) and there must 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. **Children's advice and duty service (CHAD)**: Telephone: 01782 235100 (Monday-Friday 8:30am-6:00pm) This is a conversation-based referral service and can be used to discuss concerns even if they do not meet the safeguarding threshold. **Emergency Duty Team:** Telephone: 01782 234234 (after 6pm) **Stoke-on-Trent City Council Adult safeguarding contact:** Telephone: 0800 561 0015 at any time Minicom: 01782 236037 For policies and procedures relating to adults, with care and support needs, across Staffordshire please refer to the Staffordshire and Stoke-on-Trent Adult Partnership Board (SSASPB) at Home (ssaspb.org.uk) If you think the child, young person or vulnerable adult is in immediate danger, please telephone 999.

Management of excluded individuals	• 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 persons 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.
Management of individuals requiring referral	• If the individual declines treatment via the pharmacy service, then the benefits and risks must be clearly explained • If the individual wishes an emergency Cu-IUD please refer to their GP or Sexual Health Clinic. (NB. not all GPs can fit Cu-IUDs). Oral emergency contraception, if appropriate, should be given at the time of the referral in case the Cu-IUD cannot be fitted or the individual changes their mind. • Where an individual's date of ovulation cannot be accurately determined, a supply of oral emergency hormonal contraception can only be made if; ➢ the pharmacist deems that it is in the best interests of the individual to receive a supply, and; ➢ the individual is specifically advised that post ovulation, oral emergency hormonal contraception may not be effective, and that further advice should be sought from their GP or Sexual Health Clinic • Advise the individual of alternative sources of treatment and provide relevant information as appropriate. • Advice given to individuals who require a referral must be recorded within PharmOutcomes
Reasons for seeking further advice from GP or Sexual Health Service	• Any condition/scenario where the pharmacist is uncertain whether a supply should be made • Individual fulfils exclusion criteria • Breast cancer • Individual declining treatment via pharmacy service

Drug Details	
Name, form & strength of medicine	Ulipristal Acetate 30mg tablets (UPA)
Legal classification	P Medicine
Storage	Store below 25C in original container
Route/method	Oral
Dosage/frequency/duration of treatment	One tablet to be taken as a single dose, within 120 hours of unprotected sexual intercourse (UPSI).

	UPA-EC can be supplied more than once in the same menstrual cycle should the need occur and it is clinically safe to do so. If the individual vomits or has severe diarrhoea within 3 hours of taking the tablet, another tablet should be taken, as long as this is within 120 hours of UPSI.
Quantity to supply/administer	One tablet to be taken as a single dose. The dose must be taken on the pharmacy premises
Cautions	**Pregnancy** If pregnancy occurs after treatment with UPA-EC, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as UPA-EC inhibits or postpones ovulation. Ectopic pregnancy may continue despite the occurrence of uterine bleeding. **Breast feeding** UPA-EC is excreted in breast milk and the effects on newborn/infants have not been studied. Breastfeeding is not recommended for one week after taking UPA-EC. There are no additional precautions for use, but any supplies made are done so at the professional discretion of the Pharmacist on duty https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/
Side Effects	Individuals may experience; • Nausea/abdominal pain/discomfort • Headaches • Dizziness/blurred vision • Pelvic pain/painful menses/breast tenderness • Tired/mood swings **Please refer to current BNF** http://bnf.org/bnf **and SPC** www.medicines.org.uk/emc **for full details** All drug adverse reactions must be reported to MHRA via the Yellow Card System. An individual presenting with a suspected serious adverse drug reaction (ADR) should be referred to their GP.
Advice/follow up treatment	• All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation remains the most effective method of emergency contraception, and can be used post-ovulation • Oral emergency hormonal contraception may not be effective post ovulation • Patient Information Leaflets should be highlighted and given to all individuals supplied with UPA-EC • Provide local guide to Sexual Health services • Individuals who vomit or have severe diarrhoea within 3 hours of taking UPA-EC should be advised to return to the pharmacy or visit their GP or Sexual Health Clinic. If the

	replacement dose would be later than 120 hours after unprotected intercourse, referral for a Cu-IUD should be advised and the tablet should not be issued • Explain mode of action, side effects, failure rates, benefits and how to take medication • UPA-EC may have minor or moderate influence on the ability to drive or use machinery; mild to moderate dizziness is common, blurred vision is uncommon. The individual should be informed not to drive or use machines if they are experiencing such symptoms. • Discuss that UPA-EC only provides contraception for the recent episode not for any other events that may occur in the future • Careful and consistent use of a method of contraception as appropriate for the remainder of this cycle or until protective effect of hormonal contraception is restored needs to be advised. In case of delayed ovulation in the cycle, there is potentially an increased risk of pregnancy later in the cycle if contraception is not used. • After taking UPA-EC, a woman should not start a hormonal contraceptive method for at least 5 days and be advised to use barrier methods or to abstain from sex until effective hormonal contraceptive cover has been achieved **(unless the situation described in the bullet point below is applicable).** Because UPA-EC binds to the progesterone receptor with high affinity, it may interfere with the action of progestogen-containing medicinal products, therefore women should be advised that when hormonal methods of contraception are started (after at least 5 days) then the usual recommended contraceptive precautions should be taken (barrier or abstinence) for a number of days, depending of the method used. A barrier contraceptive should be used for a further seven days (9 days for Qlaira) if using combined hormonal contraception (CHC) or for a further 48 hours for oral progestogen only contraception (POP). • 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) UPA-EC may be offered, now with immediate restart of CHC and use of condoms for seven days **(new recommendation for this specific scenario only)** • Changes to menstrual cycle (period may be early or late but most will have their next period within 7 days of the expected time) • Individuals who receive UPA-EC should be advised to have a pregnancy test within 3 weeks of taking UPA-EC or if the next period is more than 7 days late or abnormal in anyway, they should go to their GP or Sexual Health clinic to exclude pregnancy. As with any pregnancy, the possibility of an ectopic pregnancy should be considered. It is important to know that the occurrence of uterine bleeding does not rule out ectopic pregnancy.

	• Individuals who receive UPA-EC should be advised to visit their GP or Sexual Health clinic to discuss on going contraception. • Discuss sexually transmitted infections and offer advice on screening and encourage condom use. • UPA-EC is excreted in breast milk and therefore breastfeeding is not recommended for one week after taking UPA-EC. During this time it is recommended to express and discard the breast milk in order to stimulate lactation. • If pregnancy has occurred following failure of UPA-EC the individual should contact their GP or Sexual Health clinic. **Please refer to current BNF** http://bnf.org/bnf/ **or SPC for full details** http://www.medicines.org.uk/emc/

Additional information for individuals before supply	
Mode of Action	Inhibition or delay of ovulation
Risks	UPA-EC has been demonstrated to be effective for EC up to 120 hours after UPSI, with no significant variation of effectiveness over this time.
If already pregnant	The individual must be advised to contact GP or Sexual Health clinic as use of UPA-EC in pregnancy is contra-indicated.
Adverse effects	• Nausea is common and up to 1 in 100 individuals are actually sick • The individual should be advised to return if they vomit within 3 hours of taking the dose because the treatment will not be effective, and they should obtain an additional supply • Changes to menstrual cycle (period may be early or late but most will have their next period within 7 days of the expected time) • If treatment fails – increased risk of ectopic pregnancy, advise client to contact GP or Sexual Health Clinic • Abdominal pain/discomfort • Headaches • Dizziness/blurred vision (reference ability to drive or use machinery) • Pelvic pain/painful menses/breast tenderness • Tired/mood swings
Advice until next period	• Discuss that UPA-EC only provides contraception for the recent episode not for any other events that may occur in the future • Careful and consistent use of a method of contraception as appropriate for the remainder of this cycle or until protective effect of hormonal contraception is restored needs to be advised. In case of delayed ovulation in the cycle, there is potentially an increased risk of pregnancy later in the cycle if contraception is not used.

Records and Follow Up	
Supply	Individuals are required to take LNG-EC in the pharmacy. They should be provided with the patient information leaflet and local guide to the Sexual Health Clinic. Sexual Health Clinics in the City of Stoke-on-Trent are run by Midlands Partnership NHS Foundation Trust (MPFT) To find out opening times ring 0300 7900 165: • Phone line open Monday-Thursday 8.30am-4pm and Fridays 8.30am-2pm Alternatively, opening times for MPFT clinics across Staffordshire can be found here: Home - Open Clinic All individuals, whether supplied with EHC or not should be given the local guide to Sexual Health Services.
Records/audit trail	• 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
Reporting adverse drug reactions	All adverse reactions (ADR) must be reported to MHRA via the Yellow Card System. An individual presenting with a suspected serious ADR should be referred to their GP.

Date last reviewed: February 2022	**Date for next review: February 2024**
Expiry date: 31st March 2024	**Version No: 3.1 / 2022**

References	Electronic Medicines Compendium - Home - electronic medicines compendium (emc) Electronic BNF - BNF British National Formulary - NICE FSRH – Clinical Guidance Emergency Contraception (amended Dec 2017) - FSRH Clinical Guideline: Emergency Contraception (March 2017, amended December 2020) - Faculty of Sexual and Reproductive Healthcare
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

Final

Register of practitioners qualified to supply Levonorgestrel 1500mcg via PGD

Operation of this PGD is the responsibility of the commissioner and service providers.

The practitioner must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments, and provided with updated documentation for use by individual practitioners.

Stoke-on-Trent City Council authorise this PGD for use by accredited Community Pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by Stoke on Trent City Council.

This page must be completed and retained by each individual Pharmacist who intends to work in accordance with this PGD.

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

Name of professional (please print)	Signature	Date of signing

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

Final