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

## Version Control

This document is only valid on the day it was printed

The current version of this document will be found on the appropriate PharmOutcomes module, and on the Staffordshire LPC website:
http://www.southstaffslpc.co.uk/services/emergency-hormonal-contraception/

## Revision History

Date of this revision: November 2019

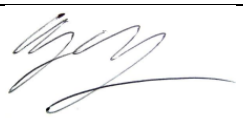
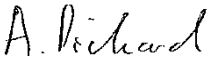
Date of next revision: Sept 2021 (or in response to new local/national guidelines)

| Version | Date | Author | Change description |
|---|---|---|---|
| 1.1 / 2017 | Sept 2017 | Andrew Pickard | N/A |
| 2.1 / 2019 | Nov 2019 | Andrew Pickard | • Inclusion criteria<br>• Exclusion criteria<br>• Management of excluded clients |

## Authorisation

This document requires authorisation by the following individuals:

| **Management** | |
|---|---|
| PGD Author | Andrew Pickard, Pharmacy Advisor – NHSE&I Midlands (Staffordshire and Shropshire) |

| **Authorisation** | | | |
|---|---|---|---|
| **Name and Designation** | **Organisation** | **Signature** | **Date** |
| Richard Harling – Lead Doctor | Staffordshire County Council |  | 20/12/2019 |
| Antony Bullock – Lead Commissioner | Staffordshire County Council |  | 19/12/2019 |
| Andrew Pickard - Pharmacy Advisor | NHS England North Midlands |  | 20/11/2019 |

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

| Staff Characteristics | |
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| 1. Professional qualifications to be held by staff undertaking PGD | • Community pharmacists accredited by the Prime Provider of the contract with Staffordshire County Council 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.<br>• Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself.<br>• Has a clear understanding of the drug to be administered including side effects and contraindications.<br>• All clinicians operating within the 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, and have completed the current CPPE training packages on Emergency Contraception and Safeguarding Vulnerable Adults and Children.<br>• Completion of the CPPE learning pack - Combating CSE: An e-learning resource for healthcare professionals.<br>• Attendance at a local training event(s) approved by Staffordshire Council is recommended where these are organised, but this is not a prerequisite for delivering the service. |

| Clinical Details | |
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| **Indication** | Postcoital Emergency Contraception |
| **Aims** | To reduce the number of unwanted pregnancies in Staffordshire by the supply of appropriate emergency hormonal contraception (EHC) to specific individuals by a community |

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| | pharmacist. |
| **Inclusion Criteria** | Clients should always be advised that the Cu-IUD is the most effective method of emergency contraception. If the client 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 client changes their mind.<br>1. The client 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.<br>2. Client 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, clients with longer menstrual cycles will ovulate later in the cycle.<br>3. If client has received Ulipristal Acetate (UPA-EC) 30mg under PGD, but has vomited within 3 hours of the dose (provided still within 120 hours of sexual intercourse)<br>4. Client weighs more than 70kg or has a BMI ≥26kg/$m^2$.<br>5. The client 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. Clients must always be offered information regarding access to comprehensive contraception and sexual health services available locally.<br>6. If the client 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.<br><br>Under the terms of this PGD it is not possible to give EHC to women as a precautionary measure for future need against unprotected sex, neither should it be supplied via a third party. |
| **Exclusion Criteria** | 1. If more than 120 hours after unprotected sexual intercourse<br>2. The client is deemed not competent as defined in the Fraser Guidance 1985.<br>3. The client is already pregnant or they think they may be pregnant<br>4. If the client has used hormonal contraception in the previous 7 days. Consider Cu-IUD or LNG-EC |

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| | 5. Any client 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.<br>6. Breastfeeding, unless willing to suspend breastfeeding for 1 week<br>7. Client's last period was late or last period was unusual (recommend a pregnancy test)<br>8. Unexplained genital bleeding or unexplained amenorrhoea<br>9. Less than 21 days following childbirth<br>10. Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.<br>**Specific medical conditions**<br>11. Severe asthma controlled by oral glucocorticoids<br>12. Diabetes Mellitus with nephropathy, retinopathy, neuropathy or vascular disease<br>13. Current liver disease or renal disease<br>14. Breast cancer<br>15. Acute active Porphyria<br>16. Malabsorption syndrome<br>17. Crohn's Disease<br>18. Known hypersensitivity to active substance Ulipristal Acetate or any other ingredient contained in the product<br>19. Hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption<br>**Medication**<br>Any drug interaction where concomitant use of UPA-EC is contra-indicated – see Appendix One BNF. This includes liver enzyme inducing drugs and drugs that increase gastric PH. |
| **Supply to young persons** | If a young person (aged <16 years) requests Emergency Contraception, then they must be assessed for competency. If they are deemed as being 'Fraser Competent' then a supply can be made, but this must be documented in the records.<br><br>Pharmacists must be aware of and comply with the relevant safeguarding expectations from Staffordshire Safeguarding Board regarding sexual activity in young people https://www.staffsscb.org.uk/Professionals/Procedures/Section-Four/Section-Four-Docs/Section-4J-Sexually-Active-Children-and-Young-People-Guidance-Final-September-2017.doc<br><br>If a child under 13 years requests Emergency Contraception, then supply can be made, but as there is therefore reasonable concern that sexual activity has taken place, the pharmacist must contact the First Response team on 0800 1313 126 (or the Emergency Duty Team on 0845 6042886 outside of office hours) |

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| **Management of excluded clients** | • If the client is excluded under the terms of this PGD, UPA-EC cannot be issued.<br>• Explain reason for exclusion and record within PharmOutcomes.<br>• If the client is currently breastfeeding and is unwilling to suspend breastfeeding for 1 week, consider a supply of LNG-EC via PGD if clinically appropriate.<br>• If the client is hypersensitive to UPA-EC, consider a supply of LNG-EC via PGD if clinically appropriate, or refer to their GP or Sexual Health Clinic.<br>• If the client 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 patients requiring referral** | • If the client declines treatment via the pharmacy service, then the benefits and risks must be clearly explained<br>• If the client 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 client changes their mind.<br>• Where a client's date of ovulation cannot be accurately determined, a supply of oral emergency hormonal contraception can only be made if;<br>➢ the pharmacist deems that it is in the best interests of the client to receive a supply, and;<br>➢ the client 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<br>• Advise client of alternative sources of treatment, and provide relevant information and contact details as appropriate.<br>• Advice given to clients who require a referral must be recorded within PharmOutcomes<br>• If the client is under 13 years of age, the Pharmacist should follow local safeguarding procedures as outlined in the 'Supply to young persons' section |
| **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<br>• Client fulfils exclusion criteria<br>• Breast cancer<br>• Client declining treatment via pharmacy service |

| **Drug Details** | |
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| **Name, form & strength of medicine** | Ulipristal Acetate 30mg tablets (UPA-EC) |

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| **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)<br><br>If client vomits 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** | There are no additional precautions for use, but any supplies made are done so at the professional discretion of the pharmacist on duty |
| **Side effects/Adverse Reactions** | • Nausea/abdominal pain/discomfort<br>• Headaches<br>• Dizziness/blurred vision<br>• Pelvic pain/painful menses/breast tenderness<br>• Tired/mood swings<br><br>**Please refer to current BNF http://bnf.org/bnf and SPC www.medicines.org.uk/emc for full details**<br><br>All serious adverse reactions must be reported to MHRA via the Yellow Card System **www.yellowcard.gov.uk** . A client presenting with a suspected serious ADR should be referred to their GP. |
| **Advice to Patients** | • Cu-IUD remains the most effective method of emergency contraception and can be used post-ovulation<br>• Oral emergency hormonal contraception may not be effective post ovulation<br>• Patient Information Leaflets should be highlighted and given to all women supplied with UPA-EC.<br>• Provide local guide to Sexual Health services<br>• Clients 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<br>• Explain mode of action, side effects, failure |

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| | rates, benefits and how to take medication<br>• 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 patient should be informed not to drive or use machines if they are experiencing such symptoms.<br>• Discuss that UPA-EC only provides contraception for the recent episode not for any other events that may occur in the future<br>• 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.<br>• After taking UPA-EC for emergency contraception, 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. Because Ulipristal Acetate 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 or for a further 48 hours for oral progestogen only contraception<br>• Changes to menstrual cycle (period may be early or late but most will have their next period within 7 days of the expected time)<br>• Clients who receive UPA-EC should be advised to have a pregnancy test within 3 weeks of taking the dose 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 |

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| | 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.<br>• Clients who receive UPA-EC should be advised to visit their GP or Sexual Health clinic to discuss on going contraception.<br>• Discuss sexually transmitted infections and offer advice on screening and encourage condom use.<br>• Women taking liver enzyme inducing drugs should be advised not to use UPA-EC during or within 28 days of stopping treatment<br>• 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.<br>• If pregnancy has occurred following failure of UPA-EC client should contact their GP or Sexual Health clinic.<br><br>**Please refer to current BNF http://bnf.org/bnf/ or SPC for full details http://www.medicines.org.uk/emc/** |

| **Additional information for clients before supply** | | |
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| **Mode of Action** | **Inhibition or delay of ovulation** | |
| **Risks** | Coitus – to – treatment interval<br>0 – 24 hours<br>0 – 72 hours<br>0 – 120 hours<br><br>Faculty of Sexual & Reproductive Health Care Clinical Guidance (2017) Emergency Contraception | Pregnancy rates<br>0.9%<br>1.4%<br>1.3% |
| **If already pregnant** | Client 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 clients actually sick<br>• Client 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<br>• Changes to menstrual cycle (period may be early or late but most will have their next period within | |

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| | 7 days of the expected time)<br>• If treatment fails – risk of ectopic pregnancy, advise client to contact GP or Sexual Health Clinic<br>• Abdominal pain/discomfort<br>• Headaches<br>• Dizziness/blurred vision (reference ability to drive or use machinery)<br>• Pelvic pain/painful menses/breast tenderness<br>• Tired/mood swings<br>** A second supply can only be made if the patient vomits within 3 hours. It is not possible to make a second supply within a single cycle if outside of this window. |
| **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<br>• 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** | |
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| **Supply** | Clients 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.<br><br>Sexual Health Clinics in Staffordshire are run by Midlands Partnership NHS Foundation Trust (MPFT)<br><br>To find out opening times in north Staffordshire (districts of Newcastle under Lyme and Staffordshire Moorlands)<br>**Telephone: 0300 7900 165**<br><br>To find out opening times in southern Staffordshire (districts of Cannock, East Staffordshire, Lichfield, South Staffordshire, Stafford and Tamworth<br>**Telephone 0300 124 5022**<br><br>Alternatively, opening times for MPFT clinics across Staffordshire can be found here:<br>http://openclinic.org.uk/ |
| **Records/audit trail** | • In discussion with the client enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at |

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| | the time of the consultation.<br>• Informed verbal consent should be obtained (for clients aged under 16 years, Fraser guidelines should be followed)<br>• If UPA-EC is supplied then the pharmacist asks the client to sign only when the pharmacist is confident that the client understands the information she has been given.<br>• 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.<br>• If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. |
| **Adverse drug reactions** | All serious adverse reactions must be reported to MHRA via the Yellow Card System **www.yellowcard.gov.uk** . A client presenting with a suspected serious ADR should be referred to their GP. |
| **Date last reviewed: November 2019** | **Date for next review: September 2021** |
| **Expiry date: 31st December 2021** | **Version No: 2.1 / 2019** |

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| **References** | BNF – Current Version<br>SPC EllaOne 30mg – HRA Pharma UK Apr 2017<br>PIL EllaOne 30mg – HRA Pharma UK Sept 2018<br>FSRH – Clinical Guidance Emergency Contraception (Amended Dec 2017) |
| **Glossary** | UPA-EC – Ulipristal Acetate 30mg tablet<br>LNG-EC – Levonorgestrel 1500mcg tablet<br>BNF – British National Formulary<br>SPC – Summary of Product Characteristics<br>PIL – Patient Information Leaflet<br>PGD – Patient Group Direction<br>FSRH – Faculty Sexual & Reproductive Health |

**Register of practitioners qualified to supply Ulipristal Acetate 30mg 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.

Lloyds Pharmacy PLC under contract to Staffordshire County 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 Lloyds Pharmacy PLC.

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 |
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**PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**