**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 authorised by Stoke-on-Trent City Council via Tier 1 service (clients aged 16+) or Tier 2 service (including clients under the age of 16 years) to provide an Emergency 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 Stoke-on-Trent City 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 Stoke-on-Trent by the supply of appropriate emergency hormonal contraception (EHC) to specific individuals by a community pharmacist. |
| **Inclusion Criteria** | Clients should always be advised that the Copper Intrauterine Device (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. |

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| | 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 (UPSI), 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.<br>3. If client has received Ulipristal Acetate 30mg (UPA-EC) 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 dose may be repeated more than once in the same menstrual cycle should the need occur<br>6. 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><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 client has used hormonal contraception in the previous 7 days, she must not be given UPA-EC. Consider Cu-IUD or LNG-EC in this circumstance. Please refer to LNG-EC PGD<br>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 |

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| | 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><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><br>**Medication**<br>20. 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 people** | 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 use their professional judgement when considering 'Safeguarding' issues related to sexual activity in young persons.<br><br>If a child under 13 years requests Emergency Contraception, and there is a reasonable concern that sexual activity has taken place, the pharmacist should:<br><br>• Refer the young person to Cobridge Integrated Sexual Health Clinic.<br>• Ring Cobridge Integrated Sexual Health Clinic to inform them of the client's attendance such that the consultation can be prioritised. Consent must be given by the client to do this<br>• always contact the local Safeguarding Lead, and |

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| | there must always be a presumption that the case will be referred to the Children's Social Care Services in the area where the child lives. |
| **Management of excluded clients** | • If the client is excluded under the terms of this PGD then they should be referred directly to Cobridge Integrated Sexual Health Clinic or their GP for further consultation.<br>• Explain reason for exclusion and record within PharmOutcomes<br>• If the client is hypersensitive to UPA-EC refer to Cobridge Integrated Sexual Health Clinic or their GP |
| **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 Cobridge Integrated Sexual Health Clinic or their GP(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 |
| **Reasons for seeking further advice from Sexual health services or GP** | • Any condition/scenario where the pharmacist is uncertain whether a supply should be made<br>• Patient fulfils exclusion criteria<br>• Breast cancer<br>• Patient declining treatment via pharmacy service |

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

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| | • Explain mode of action, side effects, failure 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 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 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 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 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 |

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| | 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/** |

Information to clients before supply

| **Mode of Action** | **Inhibition or delay of ovulation** | |
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| **Risks** | Coitus – to – treatment interval<br>0 – 24 hours<br>0 – 72 hours<br>0 – 120 hours | Pregnancy rates<br>0.9%<br>1.4%<br>1.3% |
| | Faculty of Sexual & Reproductive Health Care Clinical Guidance (2017) Emergency Contraception | |
| **If already pregnant** | Client must be advised to contact GP or Integrated 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 7 days of the expected time)<br>• If treatment fails – risk of ectopic pregnancy, advise client to contact GP/ ISHC to ensure it is | |

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| | not ectopic<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 |
| **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 UPA-EC in the pharmacy. They should be provided with the patient information leaflet and local guide to Integrated Sexual Health clinics.<br><br>Cobridge Integrated Sexual Health Clinic 0300 7900 165<br><br>www.staffordshireandstokeontrent.nhs.uk/services/cash.htm<br><br>All clients whether supplied with EHC or not should be given the local guide to Integrated Sexual Health clinics. |
| **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 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 |

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| | 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: Mar 2018 | Date for next review: Mar 2018 |
| Expiry date: Mar 2020 | Ref Code: |

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| **References** | BNF 74<br>SPC EllaOne 30mg – HRA Pharma UK December 2016<br>PIL EllaOne 30mg – HRA Pharma UK December 2016<br>FSRH – Clinical Guidance Emergency Contraception 2017 |
| **Glossary** | UPA-EC Ulipristal Acetate Emergency Contraception<br>LNG-EC Levonorgestrel Emergency Contraception<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 |

| **Management** | |
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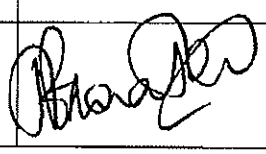
| PGD Group | Andy Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire<br><br>Dr Sally Pickard, Associate Specialist Sexual Health – Staffordshire and Stoke on Trent NHS Partnership Trust<br><br>Tania Cork, Chief Officer, North Staffordshire and Stoke-on-Trent Local Pharmaceutical Committee<br><br>Jo Bradley, Senior Health Improvement Specialist - Stoke-on-Trent City Council |

**Authorisation**
This PGD has been approved by:

| Name and Designation | Organisation | Signature | Date |
|---|---|---|---|
| Dr Paul Edmondson-Jones, Interim Director of Public Health and | Stoke on Trent City Council |  | 10.5.18. |

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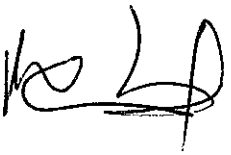
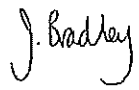
| Adult Social Care<br><br>(Lead Doctor) | | | |
| Dr Manir Hussain, Associate Director – Medicines Optimisation<br><br>(Lead Pharmacist) | Stoke on Trent Clinical Commissioning Group |  | 7.6.18. |
| Fiona Ledden, Assistant Director of Governance | Stoke-on-Trent City Council |  | 10.5.18 |
| Jo Bradley, Senior Health Improvement Specialist | Stoke-on-Trent City Council |  | 08.05.2018 |