ISLE of WIGHT COUNCIL

NHS
Isle of Wight Clinical Commissioning Group

PATIENT GROUP DIRECTION

The supply of

Ulipristal Acetate 30mg Tablet

by registered Accredited Community Pharmacists for

For Emergency Hormone Contraception (EHC)

in Community Pharmacy for Isle of Wight NHS Services

This Patient Group Direction (PGD) must only be used by registered Pharmacists 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.

Version number: 4

Change history

Version number	Change details	Date
v1	Draft Formatted into standard template	29/4/14
v4	Final amendments following review by Public Health and Community Pharmacy	21/11/14

PGD approval date/ Valid from:	**1/4/15**
Local authority implementation date:	**1/4/15**
Local authority signature:	(DPH LA)
Review date:	**1/4/17**
Expiry Date:	**1/4/17**

NHS
Isle of Wight

PGD Ref No. – EHC 2.4

PGD Accountability Record

PGD Development Group

Name	Job title and organisation	Signature	Date
Beth Shaw	Lead author – Medicines Management Pharmacist CCG		26/1/15
Dr David Turner	Lead doctor		30.1.15
Paul Jerram	Lead pharmacist – Head of Medicines Management CCG		11.2.15
Teresa Day	CCG Medicines Management Lead Nurse		17.3.15
Lauren Stott	Public Health Development Commissioner		6/3/15
Kevin Noble	Pharmacist Representative		

PGD Authorisation

This PGD has been approved and authorised for use by:

Commissioning organisation

Name	Authorising Professional	Signature	Date
Dr John Rivers	CCG Executive Chair & Clinical Lead		20/3/15
Mr Paul Jerram	CCG Prescribing/ ~~Pharmacist Lead~~		11/3/15
~~**Ms Karen Morgan**~~ Loretta Kinsella	CCG Quality and Patient Safety Lead Director of Quality & Clinical Services		24/2/15
Dr Rida Elkheir	A. Director of Public Health		26/3/15

Provider Organisation (adoption if needed)

	Name	Authorising Professional	Signature	Date
For Pharmacy company employed staff only:		Manager of healthcare professional		
For Primary Care Practice staff only:		GP/ Authorising professional		

Training and competency of registered Pharmacists

	Requirements of registered Pharmacists working under the PGD
Qualifications and professional registration	Registration with General Pharmaceutical Council of Great Britain

Initial training	• Understanding what a PGD is and how to work under a PGD
	  • GPhC codes of Professional Conduct
	  • Legal framework of PGD's
	  • Medicine, Ethics and practice – Royal Pharmaceutical Society
	• Completion of CPPE distance learning on Emergency Contraception
	• Understanding of the Fraser Guidelines for talking to under 16's about contraception
	• Understand local policies of documentation for assessing under 16's suitability for EHC under the Fraser Guidelines

Competency assessment	• Certificate of completion of CPPE training programme:
	  • CPPE Emergency Contraception certificate (e-assessment)
	  • CPPE Contraception certificate (e-assessment)
	  • CPPE Safeguarding children and vulnerable adults certificate (e-assessment)

Additional requirements	• Access to supplies of Ulipristal Acetate 30mg Tablets • Access to British National Formulary • Organisational policy on operating under PGD's • Be willing to take part in clinical audit records
Ongoing training and competency	All pharmacists are accountable for maintaining and improving their professional knowledge and competence. This must be demonstrated in accordance with the GPhC codes of professional conduct

Retain a copy of each version of the Patient Group Direction for ten years. A copy of this PGD should be given to the CCG, the healthcare professional(s) listed above, their manager(s) and the original is to be retained by the Prescribing Advisor/ Manager.

The supply of Ulipristal Acetate (UPA) 30mg tablets by registered Accredited Community Pharmacist(s) for Emergency Hormone Contraception (EHC) in Community Pharmacy for Isle of Wight NHS Services

Clinical condition

Clinical condition or situation to which this PGD applies	To provide a female presenting at a pharmacy with emergency hormonal contraception (EHC) To provide oral hormonal emergency contraception to female clients: • Aged 13 years and over who presents in person at the Pharmacy • To prevent an unwanted pregnancy following unprotected sexual intercourse (UPSI) • Request it within 120 hours following unprotected sexual intercourse (UPSI)
Inclusion criteria	• Any female aged 13 or over presenting in person for Emergency contraception up to 120hrs (5 days) after an episode of unprotected sexual intercourse (UPSI) or potential failure of regular contraceptive method, where the option of: o copper intra-uterine device (IUD) is not available, not accepted or not appropriate. o levonorgestrel is not accepted or not appropriate e.g. over the 72 hour threshold or requested at a less efficacious time in cycle; Hypersensitivity reaction to levonorgestrel. • Any female previously presenting for EHC who has vomited within 3 hours of taking a dose of EHC and is still within 120hrs of UPSI • Informed consent has been given • No earlier episodes UPSI within this cycle • Includes UPSI 21 days or more post-partum. • Female has no contraindications or exclusions to UPA • For Clients under 16 the conditions of the Fraser Guidelines must be understood and met.
Exclusion criteria	• Under 13 years of age refer such clients to local child protection/safeguarding services • Under 16 years of age and assessed as not competent using Fraser guidelines refer such clients to local child protection/safeguarding services • Known or suspected pregnancy • Known hypersensitivity to any constituent of the UPA tablet: ulipristal acetate, lactose, povidone K30, croscarmellose, magnesium stearate, • More than 120 hours since UPSI • Other episode of UPSI since last menses • Previous use of UPA or levonorgestrel (LNG) emergency contraception since last menses • Not recommended for use in women with severe asthma (stage 5 according to the British Thoracic Society Guidelines2) insufficiently

Exclusion criteria continued….	controlled by oral glucocorticoid • Renal or hepatic dysfunction (no data, no studies) • Hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption • Severe malabsorption e.g. active Crohn's disease • Informed Consent has NOT been given **Interacting medicines** [see BNF for full list] Individuals using liver enzyme-inducing drugs or within 4 weeks of stopping them:- • CYP3A4 inducers include rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoin, nevirapine, oxcarbamazepine, primidone, rifabutin, St Johns Wort (hypericum perforatum), [ritonavir] • Do not use in women currently taking drugs that increase gastric pH e.g. antacids, histamine H2 antagonists e.g. ranitidine, cimetidine, nizatidine or proton pump inhibitors e.g omeprazole, lansoprazole, pantoprazole, esomeprazole.

Cautions (including any relevant action to be taken)	**Additional precautions with hormonal contraceptives:**
	• UPA interferes with the action of progestogen containing contraceptives.
	• Contraceptive action of combined hormonal contraceptives and progestogen-only contraception may be reduced.
	• Continued use of regular hormonal contraception is not contraindicated but it is recommended by the manufacturer that reliable barrier contraception is used until the next menstrual period.
	• FSRH (Faculty of Sexual and Reproductive Health) advises females should use additional contraceptive precautions (condom or avoidance of sex) after use of UPA for:
	  • 14 days for Combined Oral Contraceptive pills
	  • 16 days for Qlaira, 9 days for Progestogen only Pill
	• Concomitant use of LNG emergency contraception and UPA is not recommended within the same cycle.
	• **Liver Enzyme Inhibitors** e.g. itraconazole, clarithromycin nefazodone: increase plasma level of UPA. The manufacturer states this is unlikely to have any clinical consequence.
	• A female breast feeding must be informed not to breast feed for 7 days after treatment. [The manufacturer advises expressing and discarding breast milk for one week]
	• Discuss with appropriate prescriber any condition or medication with which the nurse is uncertain, e.g.unexplained vaginal bleeding, current breast cancer, acute porphyria

Arrangements for referral for medical advice	• Refer to female's registered GP or alternative provider of sexual health services. • All under 16s are strongly encouraged to be referred to the Young People's Sexual Health Nurse at the IOW NHS Trust through PharmOutcomes if client consents. If client does not consent client can still access EHC.
Action to be taken if patient excluded	• Discuss other options of EHC available – Levonorgestrel or Cu-IUD • Sign-post to female's registered GP or the sexual health service for further advice and support. • Discuss possibility for the client to return to the pharmacy for pregnancy test, if necessary.

	• Supply condoms and counsel on alternative methods of contraception available.
Action to be taken if patient declines treatment	• Record advice given and any reason for declining treatment on PharmOutcomes. • Offer to refer to SHS (sexual health services) clinic for appointment with doctor or prescriber and for further advice and support • Supply condoms and make appointment for follow-up, including option of pregnancy test and STI screening options

Details of the medicine/ Description of treatment

Name, form and strength of medicine *Include ▼for black triangle medicines*	Ulipristal Acetate 30mg tablet
BNF Chapter Category	7.3.5
Legal category	POM – Prescription Only Medicine
Indicate any off-label use (if relevant)	Not applicable
Dose and frequency	30mg tablet as a single dose (STAT)
Route/method of administration	Oral with water; with or without food Administration under supervision highly recommended
Total Quantity to be administered and/or supplied	One 30mg tablet in the original packaging
Maximum or minimum treatment period	Single tablet for a single course of treatment Maximum one course per cycle
Adverse events and side effects	Refer to current BNF or SmPC for full details: **Common adverse effects** = headache, dizziness, nausea, vomiting, abdominal discomfort or pain, back pain, myalgia, dysmenorrhea, pelvic pain, breast tenderness, fatigue, mood disorders, bleeding (not related to menses). NB:- Bleeding patterns may be temporarily disturbed and spotting may occur. Most women will have their next period within 7 days of the expected time (early or late). 18.5% of women will have a delay of more than 7 days. Female must be counselled on these events and how best to manage them. A female presenting with any rarer or more severe side effects must be

	referred to their GP for review and assessment *N.B. Emergency post coital intrauterine device (Cu-IUD) should always be considered as a more effective alternative when emergency contraception is required.* **Uncommon** Vaginitis, Vaginal discharge, Nasopharyngitis, Influenza, Chills, Malaise, Somnolence, Urinary tract infection, appetite disorder, dry mouth, Emotional disorder, Irritability, anxiety, insomnia, Hyperactivity disorder, Libido changes, Migraine, Visual disturbance, Hot flush, pyrexia, Diarrhoea, Constipation, Dyspepsia, Flatulence, Acne, Skin lesion, Pruritus, Menorrhagia, Menstrual disorder, Metrorrhagia, Vaginal haemorrhage, Premenstrual syndrome, pain **Procedure for reporting Adverse Drug Reactions (ADRs)** All ADRs/ significant events/ near misses occurring in relation to the administration of this medicine under the PGD must be reported in the clinical record and the CCG incident reporting system. The GP must be informed and, in a case requiring hospital admission or resulting in serious harm, the incident reported on a yellow card to the Committee on the Safety of Medicines (CSM) - http://www.bnf.org/bnf/bnf/current/yellow.htm.
Records to be kept	The following should be recorded in client's notes on PharmOutcomes: • Patient's name address, date of birth and consent given • Assessment of client need in relation to the intervention • Including normal cycle length, timing of UPSI within cycle, details of contraceptive failure, use of medications • If under 16 years of age document compliance with the criteria of Fraser Guidelines • Date and time of supply • Dose given • Batch number and expiry date of tablet(s) • Advice given and leaflets supplied • Signature, printed name and designation of nurse who supplied the medication • Known EC failure after Ulipristal should be documented • Any ADR's should be documented The pharmacist must keep a record of the consultation for at least 8 years for an adult and 25 years for a child or for 8 years after death.

Written information to be given to patient	• The importance of taking the dose of ulipristal as soon as possible after supply • Client is aware that ulipristal acetate (UPA) is a new drug with limited evidence regarding foetal abnormality if it fails to prevent pregnancy • If under 16 years of age must be assessed as competent under the Fraser Guidelines • Advise on STI avoidance - Emphasising that EHC does not offer any protection against sexually transmitted infections and that condoms are the only means of contraception that also provide protection against these. Offer supply of free condoms. • Clinician to ensure client has been made aware of and signs the emergency contraception consent form • Provide patient information leaflet (ulipristal acetate PIL) and FPA emergency contraception leaflet • Explain option of postcoital Cu-IUD fitting instead of UPA, or LNG. The patient should be fully counselled about the effectiveness of UPA, LNG and IUD in order to make an informed choice. • Cu-IUD failure rate is considerably less than 1% (2), and may be removed 3-6 weeks after insertion • Mode of action of UPA, a progesterone receptor modulator which primarily inhibits or delays ovulation. • UPA does not prevent every pregnancy. Documented failure rates in trials:- • 1.36% if given within 72hours of UPSI, • Up to 2.1% between 48-120hours after UPSI (ellaOne SPC). • A meta-analysis of trials of emergency contraception [FSRH (2)] excluding women aged over 35years showed that hormonal EC given between 1-120hours after UPSI had a failure rate of 1.3% with UPA 30mg and 2.2% with LNG 1.5mg. • Female should return for another tablet if vomiting occurs within 3 hours of taking UPA. • To avoid driving if experience uncommon adverse effects e.g. Dizziness, blurred vision, somnolence • Need for ongoing contraception. EC with UPA should not replace a regular contraceptive method • Although the use of UPA does not contraindicate the continued use of regular hormonal contraception, UPA may reduce its contraceptive action. • Therefore, after using UPA, it is recommended that subsequent acts of intercourse be protected by a reliable barrier method for a period of time as per FSRH quick starting guidance (5) - • Combined oral contraceptive pill, transdermal patch and vaginal ring 14 days • Progestogen-only pills 9 days • Qlaira 16 days • Progestogen-only implant 14 days • Progestogen-only injectables 14 days • Use of barrier contraception or avoidance of sex covers the week after

	taking UPA plus the time required for contraceptive efficacy to be established • No known effects on the foetus if UPA fails to prevent pregnancy, but information is extremely limited. If pregnancy occurs outcome should be reported. • UPA EC only gives protection for the current risk. • To seek medical advice if low abdominal pain occurs (consider ectopic pregnancy but the chance of this is not increased) • To return for pregnancy test 21 days after last UPSI if next period is lighter, shorter or delayed more than 7 days. • Additional information to women who are breastfeeding: • It is unknown if active ingredients can pass into breast milk, but it is thought to be likely • The risk to a breastfed child from ingestion of UPA is unknown • Advise to avoid breast feeding for one week after taking UPA • Advise that further information is available online from the FPA website, Wish-Net and NHS Choices.
Follow-up advice to be given to patient	• Advise to attend sexual health service for follow up if required for a pregnancy test, STI screening, contraception or if any concerns with contraception. • If the patient vomits within 3 hours of taking the tablet she should return for a further dose to be supplied as long as the second dose still falls within the 120-hour limit. • Advise the female to see a clinician if next period is more than 7 days late, if she experiences any lower abdominal pain or if period is abnormal in any way. • If pregnancy is known to have followed UPA administration a MHRA yellowcard (www.yellowcard.gov.uk) should be completed and HRA Pharma European register of pregnancies exposed to UPA - ellaOne®

Healthcare professionals' agreement to practise

Agreement by Registered Pharmacist(s) within.....(*company name*) to administer in accordance with the Ulipristal Acetate (UPA) 30mg tablets for Emergency Hormone Contraception Patient Group Direction (PGD)

I hereby confirm that I have read the above PGD and its supporting documents. I have the appropriate training and competency to safely carry out the procedures and practices mentioned above and I agree to supply the medicine in accordance with this directive:

Name	Position; Qualifications and professional registration number	Signature	Date	Reaccreditation Date	Name of Senior representative of company authorising Pharmacist	Signature	Date

Business address Of Pharmacy operating Under PGD: _____

Appendix 1

Key references

1. Summary of Product Characteristics –Ulipristal Acetate 30mg tablets
2. British National Formulary (BNF)
3. General Pharmaceutical Council (GPhC) - Codes of Professional Conduct
4. Royal Pharmaceutical Society (RPSGB) - Medicines, Ethics and Practice (*most up-to-date version)*
5. CPPE Training package on Emergency Contraception
6. Fraser Guidelines and Gillick competence DOH
7. NICE Good Practice Guidance 2 – Patient Group Directions. Aug 2013
8. NICE Good Practice Guidance 2 – PGDs' competency frameworks. Jan 2014
9. Isle of Wight NHS Trust Sexual Health Services: Contraception PGD Cover Suite
10. Emergency Contraception, Faculty of Sexual and Reproductive Healthcare (FSRH) CEU Clinical Guidance , August 11 (updated January 2012) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf or latest edition via http://www.fsrh.org/
11. Combined Hormonal Contraception, FSRH CEU Clinical Guidance. COC - missed pills p7-8. October 2011. http://www.fsrh.org/pdfs/CEUGuidanceCombinedHormonalContraception.pdf
12. MHRA PAR Combined Oral contraceptives (the pill): when to start taking the pill and missed pill advice. May 2011 http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con117375.pdf
13. FSRH CEU Guidance. Quick starting Contraception September 2010 via http://www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf
14. How many pills have you missed. FPA http://www.fpa.org.uk/media/uploads/helpandadvice/contraception-booklets/how-many-pills-have-you-missed-chart.pdf
15. Your guide to emergency contraception. FPA http://www.fpa.org.uk/media/uploads/helpandadvice/contraception-booklets/emergency-contraception-your-guide.pdf
16. Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health. Gateway reference Number 3382. 29 July 2004 http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4086914.pdf
17. FSRH Clinical Effectiveness Unit. Clinical Guidance January 2011. Drug Interactions with Hormonal

Contraception, updated January 2012
http://www.fsrh.org/pdfs/CEUGuidanceDrugInteractionsHormonal.pdf

18. FSRH Clinical Effecitiveness Unit CEU Statement (May 2011) Missed Pill recommendations http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf

19. British National Formulary. BMJ Group & Royal Pharmaceutical Society of Great Britain. Current edition http://www.medicinescomplete.com/mc/bnf/current/index.htm

20. Q&A 399.1 Emergency contraception and breast-feeding UKMI. March 2012. Accessed via www.evidence.nhs.uk . http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Medicines%20Q%20&%20A/QA399-1_EmergContracepBM_final.doc

21. Use of Ulipristal Acetate (ellaOne®) in Breastfeeding Women FSRH March 2013 http://www.fsrh.org/pdfs/CEUstatementUPAandBreastfeeding.pdf

22. Statement on Drug Interactions between Hormonal Contraception and Ulipristal Products: ellaOne® and Esmya http://www.fsrh.org/pdfs/CEUstatementEsmya.pdf

23. Emergency contraception. NHS Choices http://www.nhs.uk/Conditions/contraception-guide/Pages/emergency-contraception.aspx#other

24. EllaOne Pregnancy Register HRA Pharma http://www.ellaone-registry.com/en/index.php

25. NICE Public Health Guidance 51 – Contraceptive Services with a focus on young people up to the age of 25 (Issued: March 2014)

Appendix 2

FRASER RULING

For clients who are believed to be less than 16 years of age, the pharmacist will assess the client's suitability for supply. Discussion with the young person should explore the following issues at each consultation. This should be fully documented and should include an assessment of the young person's maturity.

ASSESSMENT OF FRASER RULING	*YES*	*NO*
Understanding of advice given:		
Encouraged to involve parents:		
The effect of physical or mental health of young person if advice/treatment withheld		
Action in the best interest of the young person:		

Pharmacist's Signature: .....

Client's signature: .....

Date: .....