Hampshire and Isle of Wight
Partnership of Clinical Commissioning Groups

PATIENT GROUP DIRECTION

The supply of **Ulipristal Acetate 30mg Tablet**

by registered, trained and accredited community pharmacists and locum pharmacists for **Emergency Hormone Contraception (EHC)**

In Community Pharmacy for Isle of Wight Public Health Commissioned 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: 6.0

Change history

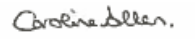
Version number	Change details	Date
1.0	Draft Formatted into standard template	29/4/14
4.0	Final amendments following review by Public Health and Community Pharmacy	21/11/14
5.0	Review	Feb 2018
6.0	Review	Jan 2020

PGD approval date/ Valid from:	**1.4.2020**
Local authority implementation date:	**1.4.2020**
Review date:	**1.1.2022**
Expiry Date:	**31.3.2022**

Ulipristal PGD Accountability Record

Verifying the PGDs on behalf of Isle of Wight Council Public Health

PGD Review Group 2020

Name	Job title and organisation	Signature	Date
Lead author & pharmacist	Caroline Allen Deputy Head of Medicines Optimisation		17.03.20
Victoria Paris	Public Health Senior Practitioner		

PGD Authorisation

This PGD has been approved and authorised for use by:

CCG Clinical Approval

Name	Authorising Professional	Signature	Date
Dr Adam Poole	Clinical Commissioning Group (CCG) GP Prescribing Lead		18.03.2020
Louise Spenser	CCG Deputy Director of Nursing and Quality		18.03.2020
Tracy Savage	CCG Locality Director and Head of Medicines Optimisation and Primary Care		17.03.2020

Verifying the PGDs on behalf of Isle of Wight Council Public Health

Name	Authorising Professional	Signature	Date
Simon Bryant	Director of Public Health Isle of Wight Council		

Provider Organisation (adoption if needed)

Name	Authorising Professional	Signature	Date

Please note:

Individuals signing as the 'manager of the healthcare professionals using the PGD' have the responsibility to ensure ALL staff working to the PGD legally recognised to do so.

Staff should be trained and competent, and their competency should be regularly updated

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 (GPhC) https://www.pharmacyregulation.org/registers/pharmacist

Initial training	• Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using:
	  ○ GPhC Standards For Pharmacy Professionals https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017.pdf
	  ○ Medicine, Ethics and Practice: Royal Pharmaceutical Society (RPS) https://www.rpharms.com/publications/the-mep
	  ○ Fraser Guidelines - Understand local policies of documentation for assessing under 16's suitability for EHC under the Fraser Guidelines
	  ○ Successful completion of self-assessment of competency form in the use of this medicine for the indications stated
	• The Pharmacist must complete electronic declaration (enrolment) via PharmOutcomes, by clicking on the Ulipristal PGD tab.

Competency assessment (CPPE Declaration of Competence)	College of Pharmacy Postgraduate Education (CPPE) distance learning: Mandatory: • CPPE e-learning Emergency Contraception 2019: https://www.cppe.ac.uk/programmes/l/ehc-e-03/ • CPPE e-learning Contraception 2019: https://www.cppe.ac.uk/programmes/l/contra-e-01/ • CPPE e-learning Safeguarding children and vulnerable adults 2019: https://www.cppe.ac.uk/programmes/l/safegrding-e-0...
Additional requirements	• Organisational policy on operating under PGD's
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 • The Pharmacist is responsible for keeping themselves aware of any changes to the recommendations for the medicine listed. • It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of their own individual scope of practice.

PGD Sign-Off Sheet 2020-22

Health professionals' agreement to practise

To be signed by individual health professionals agreeing to practice under the PGD.

I have read and understood the patient group direction, completed the prerequisite training and agree to supply and/or administer this medicine only in accordance with this PGD.

Pharmacist Name	GPhC Number	Date	Signature

Retain a copy of each version of the Patient Group Direction for ten years.

A copy of this PGD should be given to the Council, the healthcare professional(s) listed above, and the original is to be retained by the Provider 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 requesting Uliprstal emergency hormonal contraception (UPA-EHC)**
	
	UPA-EHC should be first-line oral EHC for women who has had UPSI:
	• Within the last 3-5 days (72 -120 hours ago)
	• Within the last 5 days if the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation.
	
	To provide oral hormonal emergency contraception to female clients:
	• Women who do not wish to conceive should be offered UPA-EHC after unprotected sexual intercourse (UPSI) :
	  ○ Aged 13 years and over (Fraser competence if under 16 years old), who present in person at the pharmacy
	  ○ Regular contraception has been compromised or used incorrectly
	  ○ Regardless of the day in the menstrual cycle
	  ○ EHC has already been used once or more during the same cycle
	  ▪ if she has already taken LNG-EHC, UPA-EHC could be theoretically less effective if taken in the following 7 days.
	• EHC can be provided if the woman has had UPSI earlier in the same cycle as well as within the last 5 days, as evidence suggests that EHC will not disrupt an existing pregnancy and are not associated with foetal abnormality. Available evidence suggests that EHC administered after ovulation is ineffective.
	• From day 21 after child birth
	• From day 5 after miscarriage, abortion, ectopic pregnancy or uterine evacuation gestational trophoblastic disease (GTD).

Inclusion criteria	• Any female aged 13 or over presenting in person for EHC within 120 hours (5 days) after UPSI or potential failure of regular contraceptive method, where the option of:
	  ○ Copper intra-uterine device (IUD) is not available, not accepted or not appropriate.
	  ○ LNG-EHC 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 LNG.
	• Any female who has vomited within 3 hours of taking a dose of EH LNG-EHC
	• Informed consent has been given
	• The woman has no contraindications or exclusions to UPA-EHC
	• For clients under 16 the conditions of the Fraser Guidelines must be understood and met.

Exclusion criteria	**Absolute contraindications to use:**

	• More than 120 hours since UPSI • 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 • UPA-EHC is not suitable for use by women who have severe asthma controlled by oral glucocorticoids. **Special considerations where the use of an IUD may be more appropriate (referral to a prescriber):** • Known hypersensitivity to any constituent of the UPA-EHC tablet (see product insert). • This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. • Severe malabsorption e.g. active Crohn's disease **Interacting medicines** [see BNF for full list] • For women using liver enzyme-inducing/inhibiting drugs or within 4 weeks of stopping them an IUD is recommended: ○ CYP3A4 inducers include rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoin, nevirapine, oxcarbamazepine, primidone, rifabutin, St John's Wort (hypericum perforatum), [ritonavir] ○ Administration of ulipristal acetate (10 mg tablet) together with the proton pump inhibitor esomeprazole (20 mg daily for 6 days) resulted in approximately 65% lower mean Cmax, a delayed Tmax (from a median of 0.75 hours to 1.0 hours) and 13% higher mean AUC. The clinical relevance of this interaction for single dose administration of UPA-EHC is not known
Cautions (including any relevant action to be taken)	**Counsel:** • **Higher weight** (>70kg) or BMI (>26kg/m^2); patients can be offered UPA-EHC if they refuse referral for an IUD with the caveat that it is less effective. • **Hormonal contraceptives** Ulipristal acetate binds to the progesterone receptor with high affinity and may interfere with the action of progestogen-containing medicinal products: ○ Contraceptive action of combined hormonal contraceptives and progestogen-only contraception may be reduced ○ Concomitant use of ulipristal acetate and LNG-EHC is not recommended • **Liver Enzyme Inhibitors** E.g. itraconazole, clarithromycin nefazodone: increase plasma level of UPA. The manufacturer states this is unlikely to have any clinical consequence

	• **Breastfeeding** Women should be advised not to breastfeed and to express and discard milk for 7 days after they have taken UPA-EHC. • **Pregnancy** UPA-EHC will not disrupt an existing pregnancy and is not associated with foetal abnormality. • **Fertility** A rapid return of fertility is likely following treatment with EllaOne for emergency contraception. Women should be advised to use a reliable barrier method for all subsequent acts of intercourse until the next menstrual period. • **Other** Refer to an appropriate prescriber any condition or medication with which the pharmacist 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 locally commissioned Sexual Health service (SHS) 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. • Offer 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. • Offer 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	7.3.3
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
Adverse events and side effects	***For full list of Adverse Drug reactions (ADR's) see British National Formulary (BNF)/ Summary of Product Characteristics (SmPC)*** **Common or very common** Abdominal pain; back pain; diarrhoea; dizziness; fatigue; gastro-intestinal disturbances; headache; menstrual irregularities; muscle spasms; nausea; vomiting **Uncommon** Blurred vision; breast tenderness; dry mouth; hot flushes; pruritus; rash; tremor; uterine spasm. After EllaOne intake menstrual periods can sometimes occur a few days earlier or later than expected. In approximately 7% of the women, menstrual periods occurred more than 7 days earlier than expected. In 18.5% of the women a delay of more than 7 days occurred, and in 4% the delay was

	greater than 20 days.
Records to be kept	The following should be recorded in client's notes on PharmOutcomes: • Patient's name address and date of birth • Patient 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 • If 17 years of age or younger, complete CSERQ4 with onward referral, where appropriate • Date and time of supply • Dose given – Ulipristal tablet 30mg • Batch number and expiry date of tablet(s) • Advice given • Name of pharmacist 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.

Client information

Written information to be offered to client (optional/back up)	**Patient Information Leaflet covering:**
	• The importance of taking the dose of ulipristal as soon as possible after supply
	• If vomiting occurs within 3 hours of taking UPA-EHC, a replacement dose should be taken immediately.
	• Explanation of options including use of IUD
	• Explanation of benefits, effects and alternatives
	• Explanation of possible bleeding pattern following use.
	• Discuss efficacy rates and that UPA-EHC is not 100% effective:
	  ○ 98.64% if taken within 72 hours of UPSI
	  ○ >97.9% if taken after 48-120 hours
	  ○ 98.7% if taken between 1-120 hours after UPSI.

Verbal follow-up advice to be given to client	• Higher weight (>70kg) or BMI (>26kg/m^2) could reduce the effectiveness of EHC. • If vomiting occurs within 3 hours of taking UPA-EHC a replacement dose should be taken immediately. • Discuss STI risk and refer to sexual health service, if necessary. • Offer supply of free condoms. • Advise to attend sexual health service for follow up if required for a pregnancy test, STI screening, contraception or if any concerns with contraception. • Seek medical advice if period is more than 5 days late, if there is lower abdominal pain or if the period is abnormal in any way. • Oral EHC does not provide contraceptive cover for subsequent UPSI and pregnancy if ovulation occurs later in the same cycle so they need contraception, use condoms reliably or to abstain from sex to avoid pregnancy. • Women requesting EHC should be given information regarding all methods of ongoing contraception and how to access these. • Contraception may be started >5 days after UPA-EHC.

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.

Appendix 1

Key references

1. British National Formulary (BNF) https://bnf.nice.org.uk/drug/ulipristal-acetate.html
2. CPPE Training package on Emergency Contraception
3. FSRH Emergency Contraception Guideline (updated March 2017) https://www.fsrh.org/news/fsrh-launches-new-emergency-contraception-guideline/
4. Fraser Guidelines and Gillick competence https://www.nspcc.org.uk/preventing-abuse/child-protection-system/legal-definition-child-rights-law/gillick-competency-fraser-guidelines/
5. NICE Public Health Guidance 51 – Contraceptive Services for under 25s (Published March 2014) https://www.nice.org.uk/guidance/ph51
6. Emc SmPC EllaOne® https://www.medicines.org.uk/emc/product/6657
7. EMC PIL EllaOne® https://www.medicines.org.uk/emc/product/6657/pil

Appendix 2

Pharmacist Payment

	PharmOutcomes
Pharmacist Clinical Consultation	£ (VAT except)
EHC supplied – Ulipristal 30mg tablet - Drug Tariff (Jan 2020)	£ (plus VAT)
Pregnancy Test given	£ (plus VAT)

Appendix 3

PharmOutcomes

The system will factor invoices:

- DM&D cost where '*EHC supplied?*' = *Yes* plus VAT at Low rate (EHC Supplied)
- £ where '*Have you*' *INCLUDES Carried out a pregnancy test if appropriate* plus VAT at Standard rate (£ including VAT) (Pregnancy Test given)
- £ per recorded service provision (VAT Exempt) (Professional Consultation)
- The system will allow data to be entered and claimed for retrospectively for 5 months (Grace period = 6 months)

Appendix 4

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: ……

Appendix 5

Child Sexual Exploitation Risk Questionnaire (CSERQ4)

	CSER 4 Questions	Yes	No
1	Have you ever stayed out overnight or longer without permission from your parent(s) or guardian?		
2	How old is your boyfriend/girlfriend or the person(s) you have sex with? Age of partner _____ Age of client/patient _____ Age difference _____ If age difference is 4 or more years, then tick 'YES'		
3	Does your boyfriend/girlfriend or the person(s) you have sex with stop you from doing things you want to do?		
4	Thinking about where you go to hang out, or to have sex. Do you feel unsafe there or are your parent(s) or guardian worried about your safety?		

OUTCOME

If the child has answered 'yes' to **one or more of questions 1-4**, then a referral should be made to Children's Services as this indicates that the child is at risk of, or experiencing, child sexual exploitation.

Please note that to make a referral to Children's Services you will need to obtain the child's name, DOB and address.

Childs Name	Address	Date of Birth

Name and Designation of staff member completing this form

Name:	**Signature:**
Position: **Organisation:**	**Date:**
Address:	**Telephone Number:**

Appendix 6

FSRH

Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)