Homerton University Hospital NHS
NHS Foundation Trust

This Patient Group Direction (PGD) must only be used by the named registered health professionals who have been employed and authorised by London Borough of Hackney (LBH) to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction for the supply and/or administration of ULIPRISTAL ACETATE 30MG EMERGENCY CONTRACEPTION (UPA-EC) by COMMUNITY PHARMACISTS WORKING IN A COMMUNITY PHARMACY contracted by London Borough of Hackney

Version number: 1.1

Change history

Version number	Change details	Date
1.1	Original	

PGD development

Name	Job title and organization	Signature	Date
Lead author	Dr Adam Croucher		12 JUN 2018
Lead doctor (or dentist)	Dr Sarah Creighton		12/6/18
Lead pharmacist(If required)	Nisha Limani		13/6/18
Representative of other professional group using PGD	Hitesh Patel (CEO City and Hackney LPC)		14/6/18

PGD authorisation

Designation	Name	Signature	Date
Director of Governance	Sheila Adam		18/5/18
Senior doctor (or dentist)	Louise Abrams		9.5.2018
Senior pharmacist	Iola Williams		16/5/18
NMP Lead	Filipe Da Silva		09/05/2018
Lead Nurse Medicine Safety	Vijay Venkateshappa		9/5/2018
Lead TB CNS	Viktoria Spong		9/5/2018
PGD comes into effect	May 2018		
PGD to be reviewed (min 2 years)	April 2020		

Training and competency of registered health professionals working under the PGD

Qualifications and professional registration	**THE COMMUNITY PHARMACIST MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT** **Registration:** The community pharmacist must be registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI)
Initial training	**Specialist qualifications and competencies** • Has successfully completed the CPPE PGD e-learning programme http://www.cppe.ac.uk/e-learning/pgd/story.html or can provide evidence that they have achieved the competency levels specified in NICE Competency Framework for Health Professionals using Patient Group Directions https://www.nice.org.uk/guidance/mpg2/resources • Has had the training which enables the pharmacist to make a clinical assessment in order to establish the contraceptive need and supply the medicine according to this PGD • Can satisfy the requirements of self-declaration of qualifications and competence to deliver Emergency contraceptive services according to the CPPE Programme for o Emergency Hormonal Contraception o Safeguarding children and vulnerable adults or • Can provide evidence of competencies achieved through other local training which delivers the equivalent knowledge. and • Pharmacists must ensure that the pharmacy where they are providing the service is contracted for this service • Have a current contract of employment with London Borough of Hackney
Competency assessment	Have been assessed as competent to use the PGDs by the PGD owner/approved persons.
Ongoing training and competency	• Has demonstrated that they are competent to provide the service • The pharmacist should ensure she/he is aware of any changes to the recommendations for this medication • Is familiar with current FSRH clinical guidelines on emergency contraception • Annual e-learning
LBH Governance	• The PGD owner/line manager is responsible for ensuring the list of signed staff permitted to use is maintained & can be inspected without notice. • Staff must ensure that the patient/service user is aware that the medicine is being supplied/administered under a PGD. This must be documented in records. **PGDs must be audited minimum of every 2 years (template)** http://intralive/our-services/services-a-z/m/medicines-management/patient-group-directions-(pgds)/audit/

Clinical condition

Clinical condition or situation to which this PGD applies	Emergency contraception
Inclusion criteria	• Any individual presenting for emergency contraception following unprotected sexual intercourse (UPSI) or failed contraceptive method and who has no contraindications to the medication • For choice of emergency contraceptive method please refer to FSRH emergency contraception decision making algorithm (see 'Cautions' below, and pages ix and x of https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/).
Exclusion criteria	**Personal Characteristics & Reproductive History** • Known or suspected pregnancy (NB a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period) • Individual under 16 years of age and assessed as not competent using Fraser guidelines • Individual 16 years of age and over and assessed as not competent to consent • Known hypersensitivity to any constituent of the UPA tablet • More than 120 hours since unprotected sexual intercourse • Less than 21 days following childbirth • Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease **Other Conditions** • Severe asthma controlled by oral glucocorticoids **Interacting medicines –see current BNF for interactions** • Individuals using systemic enzyme-inducing drugs/herbal products or within 4 weeks of stopping them • Individual currently using drugs that increase gastric pH (e.g. antacids, histamine H2 antagonists and proton pump inhibitors)
Cautions (including any relevant action to be taken)	• Emergency post coital intrauterine device (Cu-IUD) should always be considered as a more effective alternative when emergency contraception is required. • In an instance where the Cu-IUD is appropriate and acceptable, continue to supply UPA-EC and signpost the patient to an appropriate health service provider (see 'Arrangements for referral for medical advice' below).

	• If individual is under 13 years of age follow local safeguarding policy • Breastfeeding is not recommended for 7 days following ingestion of UPA, advise the individual to express and discard the breast milk during that time • If the individual vomits within three hours from ingestion, a further dose may be given • The effectiveness of UPA-EC may be reduced if a woman takes progestogen (including levonorgestrel emergency contraception LNG-EC) in the week prior to and five days following UPA-EC. Consider Cu-IUD or LNG-EC in this circumstance • If considering quick starting hormonal contraception LNG-EC may be preferable • It is recommended that hormonal contraception should not be used for five days after UPA, then (re)started. A barrier contraceptive should be used for a further seven days (9 for Qlaira®) if using combined hormonal contraception or 48 hours for oral progestogen-only contraception • If UPSI occurs within five days of UPA-EC, Cu-IUD should be offered if appropriate, or a further dose can be given • A pregnancy test is advised three weeks after UPSI • If community pharmacist has any concerns, discuss with appropriate health service provider • Provide written advice on ongoing contraceptive methods

Arrangements for referral for medical advice	Medical advice will be available within clinic hours at Homerton Sexual health Services (Homerton University Hospital, Clifden Centre) by telephone and by email. huh-tr.sexualhealthadvice@nhs.net 0208 510 7880. Patients can be referred to attend HSHS clinic, or advice can be provided to the pharmacist. Clinic opening hours can be found at http://www.homerton.nhs.uk/our-services/services-a-z/s/sexual-health-services/opening-times/ Out-of-hours, if medical advice is needed, the patient can be referred to Homerton Accident and Emergency.
Action to be taken if patient excluded	• Refer to appropriate health service provider • Discuss /offer alternative emergency contraceptive method • If individual is under 13 years of age follow local safeguarding policy • For individuals aged 14 to 17, and those excluded on grounds of competence, consider if safeguarding action is needed • Document all actions taken
Action to be taken if patient declines treatment	• Refer to appropriate health service provider • Discuss /offer alternative emergency contraceptive method • Document all actions taken • Record the refusal in the relevant patient record • Signpost/refer to appropriate health service provider with information about further options

Details of the medicine

Name, form and strength of medicine *Include ▼ for black triangle medicines*	Ulipristal acetate 30mg tablet
Legal category	Pharmacy Only Medicine (P)
Indicate any off-label use (if relevant)	Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes unlicensed use in the following conditions: • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption
Route/method of administration	Oral
Dose and frequency	Single dose Can be repeated within the same menstrual cycle if required
Quantity to be administered and/or supplied	Original pack of one tablet
Maximum or minimum treatment period	Single dose
Adverse effects	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. This list may not represent all reported side effects of this medicine. **Side effects may include:** **Common,** • Gastro-intestinal disturbances (including nausea, vomiting) • Abdominal pain and discomfort • Dizziness • Headache • Fatigue • Mood changes • Breast tenderness • Dysmenorrhoea • Pelvic Pain • Myalgia • Back pain **Uncommon** • Acne • Libido change • Migraine In the event of untoward or unexpected adverse reactions:

	• If necessary seek appropriate emergency advice and assistance • Document in the individual's medication record • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0800 731 6789 or online at www.yellowcard@mhra.gov.uk. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.

Records to be kept	The authorised community pharmacist must ensure the following is documented in the individual's medical record on PharmOutcomes: • Individual's name, address and date of birth • GP contact details if registered • Attendance date • Reason for attendance • Relevant past and present medical history, including drug history, and including the number of hours elapsed since UPSI last took place • Any known allergy • The consent of the individual • If individual is under 13 years of age, record action taken • If individual is under 16 years of age document competency using Fraser guidelines (if not competent, record action taken) • If individual is 16 years of age and over and not competent, record action taken • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply is by using a PGD • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any supply outside the terms of the product marketing authorisation • Record the name/brand, dose of the medication and quantity supplied • Record batch number and expiry date according to local policy or national guidelines • Any referral arrangements • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the community pharmacist supplying the medicine

Patient information

Written information and advice to be given to patient or carer	• Provide Manufacturer's Patient Information Leaflet (PIL) and discuss • Explain mode of action, side effects, and benefits of the medicine and how to take the medicine • Advise that the medicine should be taken immediately • Explain that the intra-uterine device (Cu-IUD) is considered a more effective method of emergency contraception and signpost to an appropriate healthcare provider after supply of UPA-EC, where appropriate and acceptable • Advise about the risks of the medication including failure rates and serious side effects and actions to be taken • Advise that oral EC may be less effective if the individual has a higher weight or BMI • Advise that oral EC is ineffective if given after ovulation • Breastfeeding is not recommended for 7 days following ingestion of UPA-EC, advise the individual to express and discard the breast milk during this time • Advise on what to do if vomits within three hours of taking the medicine. • Women using hormonal contraception must be aware that there may be an interaction with their current form of contraception and it is recommended that they do not take their hormonal contraception for five days after UPA, then (re)start and use barrier contraception according to method guidance. • Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/product/emergency-contraceptive-methods-booklets • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections • Discuss ongoing contraception and provide written advice on all methods • Advise a pregnancy test three weeks after treatment especially if period is delayed or abnormal, or if using hormonal contraception which may affect bleeding pattern • Ensure the individual has contact details of local contraceptive services or sexual health services
Follow-up advice to be given to patient or carer	• Individual to attend appropriate health service provider if period is delayed, absent or abnormal or if she is otherwise concerned • Individual to attend appropriate health service provider for ongoing contraception and STI screening as required

	• Pregnancy test as required (see advice to individual)

Appendices

Appendix A Key references

1. ellaOne. Manufacturer's Summary of Product Characteristics. HRA Pharma UK and Ireland https://www.medicines.org.uk/emc/medicine/22280/SPC/ellaOne+30+mg/ Updated 30.01.2017 accessed 28/02/2018
2. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <http://www.medicinescomplete.com accessed 28/02/2108
3. National Institute for Health and Care Excellence (2013). Patient Group Directions. Medicines Practice Guidelines 2 http://www.nice.org.uk/guidance/MPG2 accessed 28/02/2018
4. Faculty of Sexual and Reproductive Healthcare (2017) Emergency contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/
5. Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for contraceptive use
6. http://www.fsrh.org/ukmec accessed 28/2/18
7. Faculty of Sexual and Reproductive Healthcare (2017) Drug Interactions with hormonal contraception http://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal accessed 28/2/2018
8. Faculty of Sexual and Reproductive Healthcare (2017) Quick Starting Contraception http://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/ accessed 28/2/2108

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine only in accordance with this PGD.

Name of health professional	Signature	Senior representative authorising health professional	Date
