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 LEVONORGESTREL 1.5mg EMERGENCY CONTRACEPTION (LNG-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 for the supply/administration of LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

PGD development

Name	Job title and organization	Signature	Date
Lead author	Dr Adam Croucher		11 JUN 2018
Lead doctor (or dentist)	Dr Sarah Creighton		12/6/18
Lead pharmacist	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		09/5/2018
Lead TB CNS	Viktoria Spong		9/5/2018
PGD comes into effect	May 2018		
PGD to be reviewed (min 2 years)			

Training and competency of registered Pharmacist 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 http://www.nice.uk/mpc/goodpracticeguidance/GPG2.jsp • 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	• Annual e-learning • 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
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 over 16 years of age and over and assessed as not competent to consent • Known hypersensitivity to any constituent of the LNG-EC • More than 96 hours since this episode of 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 • Less than 5 days following ingestion of ulipristal acetate emergency contraception (UPA-EC) • Acute porphyria
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 emergency oral hormonal contraception and refer the patient to an appropriate health service provider (see 'Arrangements for referral for medical advice', below). • Ulipristal emergency contraception (UPA-EC) is more effective than LNG-EC • Consider ulipristal if the individual presents in the five days leading up to expected day of ovulation • Consider UPA-EC or double dose LNG-EC if individual has a BMI of ≥26kg/m^2 or weighs 70kg or more • If under 13 years of age follow local safeguarding

	policy • If individual vomits within three hours from ingestion, a repeat dose may be given • The dose may be repeated more than once in the same menstrual cycle should the need occur - there is no limit to the number of doses a patient may receive within a given menstrual cycle. • If community pharmacist has any clinical concerns, discuss with appropriate health service provider • Interacting medicines (not enzyme inducers) –see current British National Formulary (BNF) • Individuals using systemic enzyme-inducing drugs or enzyme inducing herbal products or within 4 weeks of stopping them, see dose/frequency section
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	• Record the refusal in the relevant patient record • Signpost/refer to appropriate health service provider with information about further options • Discuss /offer alternative emergency contraceptive method • Document all actions taken

Details of the medicine

Name, form and strength of medicine *Include ▼for black triangle medicines*	Levonorgestrel 1.5mg tablet
Legal category	Prescription Only Medicine(POM)/Pharmacy Only Medicine (P)
Indicate any off-label use (if relevant)	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) 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 • Severe hepatic impairment • Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg • Individuals with previous salpingitis or ectopic pregnancy • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption
Route/method of administration	Oral
Dose and frequency	• A single tablet to be taken immediately and within 96 hours of UPSI • Can be repeated within the same menstrual cycle if required **Dose for those individuals taking systemic enzyme inducing medications or enzyme inducing herbal products** An individual who requests levonorgestrel whilst using enzyme –inducing drugs or within four weeks of stopping them, should be advised to take a total of 3 mg levonorgestrel (two 1.5mg tablets) as a single dose **Dose for those individuals with BMI over 26kg/m^2 or weight over 70kg** Because there is evidence that 1.5mg levonorgestrel is less effective for women who fall into this category, an individual who falls into this category may be advised to take a total of 3 mg levonorgestrel (two 1.5mg tablets) as a single dose (see pages ix and x and section 9.2 of FSRH guidance https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017)

Quantity to be administered and/or supplied	Original pack of one tablet (or two original packs if taking enzyme inducing medication or high BMI/weight)
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 further information This list may not represent all reported side effects of this medicine **Common side effects** • Nausea • Low abdominal pain • Fatigue • Dizziness • Headache • Diarrhoea/vomiting • Breast tenderness Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next menstrual period within seven days of the expected time. In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's medical 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. Alternatively search for 'MHRA yellow card' in Google play or Apple app store. 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 records 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 • Advise that the medicine should be taken immediately • Explain that the Cu-IUD is considered a more effective method of emergency contraception and signpost to an appropriate healthcare provider after supply of LNG-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 • Advise on what to do if vomits within three hours • Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/sites/default/files/emergency-contraception-your-guide.pdf • 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 • If taking hormonal contraception, explain that a barrier method (i.e. condoms or diaphragms) must be used until it becomes effectiveAdvise 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 /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 above advice to patient or carer)

Appendices

Appendix A Key references

1. Levonelle 1500 microgram tablet; Summary of Product Characteristics Updated - 12.12.17 Bayer plc; Accessed 08.04.18 https://www.medicines.org.uk/emc/medicine/16887/SPC/Levonelle+1500+microgram+tablet/
2. Upostelle 1500 microgram tablet :Summary of Product Characteristics Updated 13.01.17 Consilient Health Ltd: Accessed 08.04.18 https://www.medicines.org.uk/emc/medicine/28337
3. Levonelle One Step: Summary of Product Characteristics Updated 06.04.17 Bayer plc Accessed 08.04.18 https://www.medicines.org.uk/emc/medicine/15227
4. Boots Emergency Contraceptive 1.5mg tablet: Summary of Product Characteristics Updated 04.04.18 Accessed 08.04.18 http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1522989040947.pdf
5. Isteranda 1.5 mg levonorgestrel. Summary of Product Characteristics Updated 24.11.2016 Sandoz Limited: Accessed 08.04.18 http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1518761915504.pdf
6. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <http://www.medicinescomplete.com accessed 08.04.18
7. National Institute for Health and Care Excellence (2013). Patient Group Directions. Medicines Practice Guidelines 2 http://www.nice.org.uk/guidance/MPG2 Accessed 16.03.2017
8. Faculty of Sexual and Reproductive Healthcare (2017) Emergency contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/
9. Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for contraceptive use http://www.fsrh.org/ukmec Accessed 16.03.2017
10. Faculty of Sexual and Reproductive Healthcare (2017) Drug Interactions with hormonal contraception http://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal
11. 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/

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