NHS
Sunderland
Clinical Commissioning Group

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

Patient Group Direction

for the supply of

UPOSTELLE (PREFERRED BRAND IN PRIMARY CARE) OR LEVONELLE LEVONORGESTREL 1.5MG TABLET

by registered nurses and pharmacists for

oral emergency contraception

in GP practices within Sunderland

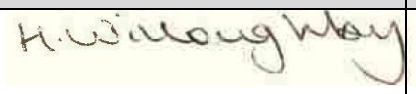
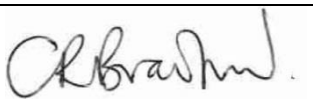
Version number: 1.4

Date PGD comes in to effect:	**January 2017**
Review date:	**January 2018**
Expiry date:	**March 2018**

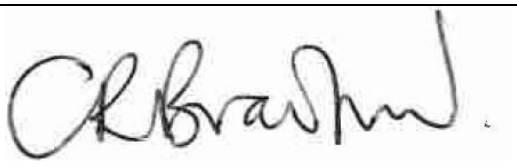
Change history

Version number	Change details	Date
V1.0	Initial approved version	March 2016
V1.2	Updated to acknowledge recent MHRA advice	October 2016
V1.3	Updated to acknowledge recent MHRA advice	January 2017
V1.4	Updated to encorporated new advice on enzyme inducers and women who have a BMI >26 kg/m^2 or weight >70 kg	June 2017

PGD development:

Name	Job title and organisation	Signature	Date
Medicines optimisation pharmacist Sunderland CCG	**Hannah Willoughby** *(Interface pharmacist)*		July 2017
Medicines optimisation pharmacist Sunderland CCG	**Juliet Fletcher** *(Senior pharmacist)*		July 2017
Practice nurse representative to the executive committee Sunderland CCG	**Florence Gunn** *(Senior nurse)*		July 2017
Medical director Sunderland CCG	**Dr Claire Bradford** *(Senior doctor)*		July 2017
Other members of the PGD working group	Not applicable		

PGD authorisation :

Name	Job title and organisation	Signature	Date
Medicines optimisation pharmacist	**Juliet Fletcher** *(Senior pharmacist)*		July 2017
Practice nurse representative to the executive committee Sunderland CCG	**Florence Gunn** *(Senior nurse)*		July 2017
Medical director, Sunderland CCG	**Dr Claire Bradford** *(Senior doctor)*		July 2017
Person signing on behalf of authorising body			

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered nurses/pharmacists

	Requirements of registered nurses/pharmacists working under the PGD
Qualifications and professional registration	**Healthcare professionals using this PGD must:** • **Have a current contract of employment with a GP practice within Sunderland CCG** • **Be currently registered with their relevant professional body** o Nurses: the Nursing & Midwifery Council (NMC) o Pharmacists: General Pharmaceutical Council (GPhC) • **And at least one of the following:** o Holds a recognised post-registration qualification in contraception/sexual health (an introduction to contraception is not sufficient). **OR** o Significant training and experience in contraception and sexual health. This should be confirmed by documentation on individuals personal file.
Initial training	• Has had training in the use of PGDs • Has had training which enables the nurse/pharmacist to make a clinical assessment in order to establish contraceptive need, supply and administer levonorgestrel 1.5 mg tablet according to this PGD. • Has undertaken the competency training appropriate to this PGD • Has been assessed and achieved the required standard deemed necessary by the senior medical representative in the practice who deems the healthcare professional competent to practice under the PGD. • Is competent in the assessment of the individuals using the Fraser guidelines • Has undergone regular training and updates in safeguarding children and vulnerable adults • Has undergone regular updates in basic life support and anaphylaxis
Competency assessment	• Must have demonstrated an appropriate level of competence to the senior medical representative in the practice in contraceptive services.
Ongoing training and competency	• The registered nurse/registered pharmacist should ensure she/he is aware of any changes to the recommendations for this medication. It is the responsibility of the healthcare professional to keep up-to-date with continuing professional development and take part in the audit of clinical records on a regular

	basis. • Continuous professional development is completed as per governing body. • Revalidation of professional qualification as dictated by governing body

Clinical condition

Clinical condition or situation to which this PGD applies	Emergency contraception
Inclusion criteria	Any individual presenting for emergency hormonal contraception within 72 hours of unprotected first sexual intercourse (UPSI) or failed contraceptive method. Note: A copper IUD should be offered to all eligible women presenting up to 120 hours after unprotected sexual intercourse or within 5 days of expected ovulation. Women who accept this measure should be excluded from this PGD • **Follow Fraser guidelines ('Gillick competence') if under 16 years** • **Follow local safeguarding policy if under 13 years of age**
Exclusion criteria	**Personal characteristics & reproductive history** • Known or suspected pregnancy • Individuals under 16 years of age and not competent using Fraser guidelines unless an appropriate adult can consent for them. • Individuals aged 16 years and over and assessed as not competent to consent using local safeguarding guidelines unless under 18 and an appropriate adult can consent for them. • Known hypersensitivity to any constituent of the progestogen only emergency contraception (POEC). See product patient information leaflet. **Other factors** • Individual wishes to see a doctor • Be mindful to exclude patients who are being influenced or coerced into having emergency contraception that is not of their own free will. • Check drug history and refer to current BNF for more details and potential drug interactions and ask for advice on management if necessary. All patients taking a medication that interacts significantly (indicated with a black dot in the paper version, or shaded red in the online version) with levonorgestrol should be excluded •

Cautions (including any relevant action to be taken)	• Emergency post coital intrauterine device (IUD) should always be considered as a more effective alternative when emergency contraception is required

	• Consider ulipristal if the individual presents between 72 and 120 hours (**note this will require referral and is not covered under the scope of this PGD).** • If under 13 years of age follow local safeguarding policy • If individual who received a single dose (1x1.5mg tablet) vomits within three hours from ingestion, a repeat dose may be given • Those who receive a double dose (2x1.5mg) who then vomit within three hours must be referred. • The dose may be repeated more than once in the same menstrual cycle should the need occur. • Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse/pharmacist is unsure/uncertain • Previous history of salpingitis or of ectopic pregnancy • Severe hepatic dysfunction • Severe malabsorption syndromes • Galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption • Women who have a BMI >26 kg/m^2 or weight >70 kg require a double dose – see dosing section for more information. • Interacting medicines –check drug history and refer to current BNF for more detail and potential drug interactions and ask for advice on management if necessary. o Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin and efavirenz. o Medicines containing levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism • See dosing section for information regarding dosage adjustments for patients on enzyme inducing medication.

Arrangements for referral for medical advice	None
Action to be taken if patient excluded	• Refer to appropriate doctor/independent nurse prescriber/sexual health facility • Discuss/offer alternative emergency contraceptive method • Re-assure and provide any practical advice. • If > 72 hours since episode of unprotected intercourse, a post-coital IUCD is an alternative option or ulipristal (ellaOne®) • Document all actions taken in clinical record
Action to be taken if patient declines treatment	• Record the refusal in the clinical record and document all other actions taken • Refer to appropriate doctor/independent nurse prescriber where required • Discuss /offer alternative emergency contraceptive method

Details of the medicine

Name, form and strength of medicine *Include ▼ for black triangle medicines*	Levonorgestrel 1.5 mg tablet (Upostelle or Levonelle)
Legal category	Prescription only medicine
Indicate any off-label use (if relevant)	See in dosing section, below
Route/method of administration	Oral
Dose and frequency	• A single tablet to be taken within 72 hours of UPSI • Repeated episodes of UPSI may be treated within one menstrual cycle • Women seeking emergency contraception who use or have used cytochrome P450 3A4 (CYP3A4) enzyme inducers within the last 4 weeks should take a double dose (2x1.5mg tablets). • Women seeking emergency contraception who have a BMI >26 kg/m^2 or weight >70 kg should take a double dose (2x1.5mg tablets). This is an unlicensed use and must be communicated to the patient.
Quantity to be administered and/or supplied	Women seeking emergency contraception who use or have used cytochrome P450 3A4 (CYP3A4) enzyme inducers within the last 4 weeks: TWO original packs of one tablet Women who have a BMI >26 kg/m^2 or weight >70 kg: TWO original packs of one tablet For all other patients: ONE original pack of one tablet
Maximum or minimum treatment period	Single supply for immediate use

Adverse effects	This list does not represent all reported side effects of this medicine. Refer to current summary of product characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. **Common side effects** • Abdominal pain 13.3% to 17.6% • Nausea 13.7% to 23.1% • Dizziness 9.6% to 11.2% • Headache 10.3% to 16.8% • Migraine 2.3% • Breast tenderness 8.2% to 10.7% • Pain in pelvis (6.1% to 6.2%) • Fatigue (13.3% to 16.7%) 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 clinical record and inform appropriate doctor/independent nurse prescriber • 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 0808 100 3352 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 registered nurse/pharmacist must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical history, including drug history • Weight and BMI • Any known allergy • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply or administration 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 referral arrangements • Any administration outside the terms of the marketing authorisation • 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 individual over 16 years of age and not competent, record action taken • Record the name/brand, dose of the medication and quantity supplied • Record batch number and expiry date according to local policy or national guidelines • 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 nurse/pharmacist supplying or administering the medicine • Confirmation the patient has been informed the medication is being used in an unlicensed way, if applicable • "Supplied under PGD"

Patient information

Written information to be given to patient or carer	• Provide manufacturer's patient information leaflet (PIL) • Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/medial/uploads/helpandadvice/contraception-booklets/emergency-contracpetion-your-guide.pdf
Follow-up advice to be given to patient or carer	• Explain mode of action, side effects, and benefits of the medicine • Advise about the risks of medication including failure rates and serious side effects and actions to be taken • Advise on what to do if individual vomits within three hours of taking the pill(s) • Offer condoms and advice on safer sex practice and possible need for screening for sexually transmitted infections • Discuss need for reliable contraception for the remainder of the menstrual cycle • When starting a hormonal method immediately after the administration of POEC, see FSRH guidance on quick starting • Discuss and offer ongoing contraception • Advise a pregnancy test three weeks after treatment. The patient does not need to reattend the clinic for this unless suspected pregnancy, as below. • Advise to return if menstrual periods are delayed by more than 5 days, abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason so pregnancy can be excluded or if otherwise concerned. • Ensure individual has the contact details of the clinic/GP practice • Individual to return to clinic/GP practice if she has any concerns • Advise individual what to do if has concerns out of hours

Appendices

Appendix A Key references

1. Patient group directions. NICE guidelines [MPG2]. August 2013
2. SPC for Levonelle One Step1500 microgram tablet. Available at: https://www.medicines.org.uk/emc/medicine/16887
3. NICE Clinical Knowledge Summary. Contraception – emergency. Last revised in February 2015
4. Royal College of Nursing and FFPRHC. Levonelle ® 1500 - Emergency Contraception Template Patient Group Direction. http://www.fsrh.org/pdfs/PGDLevonelle1500.pdf
5. London contraception and sexual health Patient Group direction for the supply of progestogen only emergency contraception (POEC) Levonorgestrel 1.5mg tablet.
6. Drugdex by Micromedex solutions, Truven Healthcare solutions
7. MHRA drug safety update September 2016 Volume 10, Issue 2 available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/553274/Sept_2016_DSU.pdf
8. SPC for Upostelle tablets. Available at: https://www.medicines.org.uk/emc/medicine/28337
9. The faculty of sexual and reproductive healthcare: FSRH guideline emergency contraception, March 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 registered nurse/pharmacist	Signature	Senior representative authorising nurse/pharmacist	Date