NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
[Registered Pharmacists]
Patient Group Direction (PGD) for supply of
Levonorgestrel 1500 micrograms tablet

1. Clinical Condition

Clinical situation/condition	Postcoital emergency contraception for use in clients presenting within 72 hours of unprotected sexual intercourse or following potential failure of hormonal and intrauterine methods of contraception. For clients supplied with barrier methods of contraception in case of failure.
Maturity of patient	Adult or young person aged 13 to 16 years of age and Fraser competent. When the client is under 16 years of age, strict adherence to the Fraser Guidelines should be applied at **each attendance.** A doctor must be consulted if there is any doubt about adherence to the Fraser Guidelines If patient under 13 years discuss with a doctor at New Croft Sexual Health and/or Safeguarding Advice and Support Team
Criteria for inclusion	Patients with no contraindications from medical history to the treatment presenting for emergency contraception within 72 hours of unprotected sexual intercourse (UPSI). Patients presenting for emergency contraception between 72 – 120 hours after first episode of UPSI who have no contraindications and where the copper intrauterine device is not appropriate.
Criteria for exclusion	• EC providers should be aware that if a woman has already taken UPA-EC, LNG-EC should not be taken in the following 5 days. • Known or suspected pregnancy • Patient at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy) • Known sensitivity to levonorgestrel

	or any constituent of the levonorgestrel tablet. • Under 16 years of age and assessed as not competent using Fraser guidelines • Enzyme-inducing medicines including barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing *hypericum* perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin, efavirenz. (see current Summary of Product Characteristics for full details) • Severe hepatic dysfunction • Severe malabsorption e.g. Crohn's disease • Galactose intolerance, Lapp Lactase deficiency or glucose-galactose malabsorption • Porphyria **Dose for those individuals taking enzyme inducing medicines or herbal remedies.** A patient who requests post coital emergency contraception while using enzyme-inducing drugs or within 4 weeks of stopping them, should be seen by a doctor at New Croft Centre, A/E or GP. A copper-IUD is the emergency contraceptive of choice. • In those patients who find a copper IUD unacceptable or unsuitable, a total of 3 mg levonorgestrel (two 1.5 mg tablets) is required as a single dose are still within 72 hours of unprotected sexual intercourse.
Additional exclusion information	Women should be informed that it is possible that higher weight (>70kg) or BMI (>26kg/m^2) could reduce the effectiveness of oral EC, particularly

	LNG-EC. UPA-EC should be offered under these circumstances EC providers should consider UPA-EC as the first-line oral EC for a woman who has had UPSI 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.
Action if excluded	Pharmacists should refer to New Croft Centre, GP or Accident and Emergency Department. Discuss/offer copper IUD as the first line emergency contraceptive method as it is the most effective option. Discuss alternative contraceptive methods including quick starting hormonal methods Document all actions taken and all advice given in clinical records
Action if patient declines treatment	Refer patient to New Croft doctor or own GP if possible Document all actions taken and all advice given in clinical records
Any other circumstances when further advice should be sought	• Cicloporin therapy – seek advice from specialist who prescribes ciclosporin as blood test(s) to check ciclosporin levels will be necessary. Discuss with appropriate doctor/non-medical prescriber any medical condition or medication of which the pharmacist is unsure/uncertain. Pharmacist must seek advice from senior A&E doctor, Paediatric Registrar or Sexual Health Team, New Croft Centre. If any Safeguarding concerns contact the Community Safeguarding Advice and Support Team and /or Children's Social Care.

Additional Information	• Levonorgestrel is secreted into breast milk. Potential exposure of an infant can be reduced by taking the tablet immediately after feeding. Avoid feeding for at least 8 hours.
	In the following circumstances LNG-EC can be supplied but the patient must be referred to a doctor for a follow-up review. • Unexplained vaginal bleeding (pregnancy must be excluded) • Known severe hypertension (BP >180/110 mmHg) • Suspicion of pregnancy although pregnancy test negative • Current severe liver disease
	Note: LNG-EC can be taken more than once in a menstrual cycle.

2. **Characteristics of Staff**

Class of health professional to whom PGD applies	Registered Pharmacist with the General Pharmaceutical Council working in community pharmacy who has completed their CPPE Declaration of Competence for EHC.
Qualifications required	**Qualifications** • Pharmacists registered with the General Pharmaceutical Council • Pharmacists will have successfully completed CPPE training on emergency hormonal contraception • Pharmacists attended programme provided and accredited by Newcastle Hospital Trust and Newcastle Public Health Team • Pharmacists have appropriate indemnity insurance • Pharmacists to have systems to protect confidential information **Specialist qualifications and competencies** • Has had training in the use of PGDs • Has had training which enables the pharmacist to make a clinical assessment in order to establish the

	contraceptive need and supply the medication according to this PGD. • Has undertaken the competency training appropriate to this PGD • Has been assessed and achieved the required standard. • Is competent in the assessment of individuals using Fraser guidelines • Has up to date mandatory training in safeguarding children and vulnerable adults and in basic life support and anaphylaxis **Maintenance of competencies** The pharmacist should ensure she/he is aware of any changes to the recommendations for this medication. It is the responsibility of the pharmacist to keep up-to-date with continuing professional development and take part in audit of clinical records on a regular basis
Continued training requirements	The pharmacist should be 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 individual's scope of practice All registered pharmacists are personally accountable for their practice and in the exercise of professional accountability there is a requirement to maintain and improve their professional knowledge and competence

3. Description of Treatment

Name of Medicine	LEVONORGESTREL 1500 micrograms
Class of medicine	Emergency Hormonal Contraceptive
Legal status	Prescription Only Medicine (POM)
Medicine is licensed for clinical condition	Yes

stated in PGD	
Route of administration	Oral
Pharmaceutical form and strength	Tablet 1500 micrograms
Dose	1 tablet
Frequency of administration	Stat dose, repeated once if vomiting occurs within 3hours of administration.
Maximum/minimum total dose to be supplied/administered	A single tablet (1500mcg) to be taken as soon as possible within 72 hours of unprotected sexual intercourse (UPSI)
Maximum/minimum period over which medicine should be administered	1500mcg within 72 hours of unprotected sexual intercourse Increased dose of two tablets (3mg) to patients taking liver enzyme inducing drugs – unlicensed but in FSRH guideline (See BNF and FSRH guidelines for list of affected drugs The dose may be repeated more than once in the same menstrual cycle should the need occur.
Common adverse effects	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) www.bnf.org.uk for further information. Side effects may include; Nausea, low abdominal pain, fatigue, dizziness, headache, diarrhoea, vomiting, breast tenderness, bleeding not related to menses, irregular menstruation, delay of menses more than 7 days (Bleeding patterns may be temporarily disturbed but most women will have their next period within seven days of the expected time)
Drug Interactions	Current Summary of Product Characteristics for LNG-EC must be checked for interactions if patient is taking any medication. If necessary check with doctor at New Croft. Drugs suspected of having the capacity to reduce the efficacy of LNG-EC by

	induction of liver enzymes include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing *hypericum* perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin and efavirenz. See 'Criteria for exclusion' section for action. Medicines containing levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism. Seek advice from a doctor at New Croft.
Action if patient is taking an interacting drug or experiences an adverse effect	**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 non-medical prescriber. Complete incident procedure if adverse reaction is severe (refer to local organisational policy If necessary seek appropriate emergency advice and assistance It is the responsibility of the pharmacist to identify a suspected ADR and to report it. 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.
Additional warnings	If vomiting occurs within three (3) hours of taking the tablet a second dose will be required and the patient must return to the pharmacist or New Croft or Walk in Centre or GP.
Information on follow-up treatment	Patient must be advised to seek advice if

	menses is delayed by seven days or is abnormal.
Pre-pack to be supplied to patient (if appropriate)	LNG-EC should be administered to the patient by the pharmacist. If barrier method of contraception is the only appropriate method of contraception however the pharmacist can supply one dose to patient as an advanced supply

4. Patient Information

Written/verbal advice for patient	EC providers should advise women that ulipristal acetate (UPA-EC) has been demonstrated to be more effective than LNG-EC. Provide product manufacturers Patient Information Leaflet and Contraception & Sexual Health Service information Discuss and document that copper IUD is most effective form of emergency contraception (EC) and that ulipristal acetate is second choice. If sign posting to external IUD fitting services give oral EC. Discuss and document factors that influence efficacy rates e.g. interval from UPSI, weight and raised body mass index (BMI) especially if BMI >30. The patient then can make an informed choice about type of emergency contraception Discuss the need for reliable contraception for the remainder of the cycle for the maximum efficacy and the future. Sign post to service offering quick start contraception if not offered in-house. Advise about the risks of the medication including failure rates and serious side effects and the actions to be taken

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If next period is 5 days overdue pregnancy must be excluded.

Advise on what to do if vomits within three (3) hours of taking the medication

Provide a copy of the FPA leaflet on emergency contraception or sign post FPA website

When starting a hormonal method immediately after the administration of LNG-EC, see FSRH guidance on quick starting

<table>
<tr><th>Patient starting or recommencing hormonal contraception</th><th>Use additional barrier method for (days)</th></tr>
<tr><td>Combined oral, vaginal ring, transdermal contraception</td><td>7</td></tr>
<tr><td>Progestogen-only Pill
Progestogen-only implant* fitted
Depo provera administered
Sayana press administered</td><td>2
7
7
7</td></tr>
<tr><td>Qlaira</td><td>9</td></tr>
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Offer condoms and advice on safer sex practices

Discuss and offer ongoing contraception

Ensure individual has the contact details of the service
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<td>Records to be completed</td>
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A record of all patients supplied with levonorgestrel under this direction will be available for audit purposes.

A full record must be kept of all stock received and issued, including manufacturer, batch number and expiry date. The following data must be
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	included: □ Issue date, patient name, drug name and strength, quantity, signature of pharmacist. The pharmacist must ensure the following is documented in the clinical record: • Individual's name, address plus postcode and date of birth • Attendance date • Reason for attendance • Past and present medical and family history, including drug history • Any known allergy • Any advice given about the medication including side effects, benefits, how to take it and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any supply outside the terms of the product licence • The consent of the individual • If individual is under 16 years of age document competency using Fraser guidelines • If individual is under 13 years of age record action taken. • Record the name of the medication, number of packs supplied i.e. levonorgestrel 1500 x 1 with batch number and expiry date. • Record any follow up arrangements • Signature and designation of the pharmacist who supplied the medication (follow local procedures for computer records)
Audit	Any drugs issued under PGD will be reviewed by the lead pharmacist on an annual basis

Patient Group direction developed by: Diana Mansour and Lesley Anne Flynn
Reviewed by: Lorna Clark and Ann Gunning

Implementation date: April 2017
Review date: April 2020

Approval of Patient Group Direction:

	Name	Signature	Date
Senior Doctor	Diana Mansour		22/5/17
Senior Pharmacist	Julia Blagburn		26/5/17
Senior Pharmacist	Ann Gunning		8/6/17
Senior Nurse	Lesley Anne Flynn		19.5.17.
Chair of NMP Group	Lorna Clark		22/5/17
Chair of MMC	Prof S Thomas		23/5/17

Patient Group Direction
COMPETENCY SELF-ASSESSMENT

Patient Group Direction (PGD) for treatment of patients in New Croft Sexual Health clinics, Pharmacies and School Health

The administration of: levonorgestrel 1500 micrograms
Indication:

Name of Pharmacist:

The pharmacist must initial below to confirm that they are able to meet all the requirements of the competency assessment.

Competency Statement	**Initial of pharmacist**	***Comments***
Identifies inclusion and exclusion criteria		
Describes actions to be taken for excluded patients		
Demonstrates an understanding of the law in relation to the PGD		
Demonstrates understanding of drug(s) used in the PGD, including their proposed actions and potential side effects, contra-indications and cautions		
Identifies correct calculation of dose in all groups of patients (if applicable)		
Describes actions to be taken in event of drug reaction		
Demonstrates correct administration and documentation		
Obtains an accurate drug history from patient including allergy status, previous drug reactions, any self medication and over the counter drugs		
Identifies and completes audit trail		

I confirm that I am able to meet all the requirements of the above assessment and I am competent to provide the medication detailed within this PGD

Name of Pharmacist and signature :

Date: Review Date:

Individuals who have been assessed competent to work in accordance with the PGD for Levonorgestrel 1500micrograms

Date PGD applicable: May 2017

Frequency of peer review: Annual

Review of PGD due: May 2020

Name	Date Assessed	Date peer Reviewed	Reviewers initial	Date peer Reviewed	Reviewers initial