

PATIENT GROUP DIRECTION

The supply of Levonorgestrel **1500mcg tablet**

by registered, accredited and authorised 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 Accredited Community 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: 7.0

Change history


Version number	Change details	Date
1.0	Draft reformatted to standard template format	29/4/14
5.0	Final amendments following review by Public Health and Community Pharmacy	21/11/14
6.0	Review	Feb 2018
7.0	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

Levonorgestrel PGD Accountability Record

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



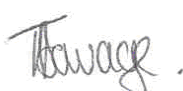
PGD Review Group 2020

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		18.03.20
Louise Spenser	CCG Deputy Director of Nursing and Quality		18.03.20
Tracy Savage	CCG Locality Director and Head of Medicines Optimisation and Primary Care		17.03.20

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	<ul style="list-style-type: none"> Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using: <ul style="list-style-type: none"> 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 Levonorgestrel PGD tab.
Competency assessment (CPPE Declaration of Competence)	<p>College of Pharmacy Postgraduate Education (CPPE) distance learning: Mandatory:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Organisational policy on operating under PGD's
Ongoing training and competency	<ul style="list-style-type: none"> 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 Levonorgestrel 1500mcg tablet by registered Community Pharmacists for Emergency Hormone Contraception in Community pharmacy for Isle of Wight NHS services

Clinical condition

<p>Clinical condition or situation to which this PGD applies</p>	<p>A female requesting Levonorgestrel emergency hormonal contraception (LNG-EHC)</p> <p>LNG-EHC can be used if it is taken within 72 hours of UPSI. If >72 hours after UPSI use Ulipristal (UPA-EHC) effective up to 120 hours.</p> <p>UPA-EHC has been demonstrated to be more effective than LNG-EHC and is the first-line choice if UPSI occurred</p> <ul style="list-style-type: none"> • 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. <p>To provide oral hormonal emergency contraception to female clients:</p> <ul style="list-style-type: none"> • Women who do not wish to conceive should be offered LNG-EHC after unprotected sexual intercourse (UPSI): <ul style="list-style-type: none"> ◦ 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 ◦ EHC has already been used once or more during the same cycle (if she has already taken UPA-EHC, LNG-EHC should not be taken in the following 5 days) ◦ Regardless of the day in the menstrual cycle (UPA-EHC is first choice option if UPSI within 5 days prior to anticipated day of ovulation) • 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).
<p>Inclusion criteria</p>	<ul style="list-style-type: none"> • Any female aged 13 years or over requesting EHC within 72 hours of UPSI or potential failure of regular contraceptive method, where the option of a copper intra-uterine device (IUD) is not available, not accepted or not appropriate. • Any female who has vomited within 3 hours of taking a dose of EHC • Informed consent has been given • The woman has no contraindications or exclusions to LNG-EHC • For Clients aged under 16 the conditions of the Fraser Guidelines must be understood and met



Exclusion criteria	<ul style="list-style-type: none"> Any female aged 13 years or over requesting EHC within 72 hours of UPSI or potential failure of regular contraceptive method, where the option of a copper intra-uterine device (IUD) is not available, not accepted or not appropriate. Any female who has vomited within 3 hours of taking a dose of EHC Informed consent has been given The woman has no contraindications or exclusions to LNG-EHC <p>For Clients aged under 16 the conditions of the Fraser Guidelines must be understood and met</p>
Contra-Indications	<p>Absolute contraindications to use:</p> <ul style="list-style-type: none"> UPSI of more than 72 hours - Ulipristal effective <120 hours 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 Acute porphyria Previous history of salpingitis or ectopic pregnancy <p>Special considerations where a supply of a double dose of LNG-EHC or the use of an IUD may be more appropriate (referral to a prescriber):</p> <ul style="list-style-type: none"> Severe hepatic dysfunction Severe malabsorption syndromes i.e. Crohn's disease. Hypersensitivity to any of the ingredients in the preparation (see product insert). Enzyme inducers: <ul style="list-style-type: none"> Phenytoin, Barbiturates (including primidone), Carbamazepine, Phenylbutazone, Rifamicin, Rifonavir and Griseofulvin can reduce the efficacy of levonorgestrel. Ciclosporin – levonorgestrel can increase ciclosporin toxicity due to inhibition of metabolism. Herbal remedies, especially remedies containing St John's Wort, (Hypericum perforatum millepertuis) This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Cautions (including any relevant action to be taken)	<p>Counsel:</p> <ul style="list-style-type: none"> Higher weight (>70kg) or BMI (>26kg/m²) – offer double dose LNG-EHC, UPA-EHC if copper IUD not appropriate Pregnancy LNG-EHC will not disrupt an existing pregnancy and is not associated with foetal abnormality. Breastfeeding Women should be informed that available limited evidence indicates that LNG-EHC has no adverse effects on breastfeeding or on their infants. Fertility After using emergency contraception it is recommended to use a local barrier method (e.g. condom, diaphragm, spermicide, cervical cap)



	<p>until the next menstrual period starts. The use of levonorgestrel does not contraindicate the continuation of regular hormonal contraception.</p> <p>Seek specialist advice:</p> <ul style="list-style-type: none"> • Active trophoblastic disease (until return to normal of urine- and plasma-gonadotrophin concentration) • Severe malabsorption syndromes <p>Other</p> <p>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</p>
Arrangements for referral for medical advice	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Discuss other options of EHC available – Ulipristal Acetate 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	<ul style="list-style-type: none"> • 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 <i>Include ▼ for black triangle medicines</i>	Levonorgestrel 1500mcg tablet
BNF Chapter Category	7.3.4
Legal category	POM – Prescription only medicine
Indicate any off-label use (if relevant)	Not Applicable
Dose and frequency	1500mcg tablet as a single dose for immediate use within 72 hours of UPSI
Route/method of administration	Oral
Total Quantity to be administered and/or supplied	One tablet in original packaging
Maximum or minimum treatment period	Single tablet for single course of treatment. Administration under supervision highly recommended.
Adverse events and side effects	<p><i>For full list of Adverse Drug reactions (ADR's) see British National Formulary (BNF)/ Summary of Product Characteristics (SmPC)</i></p> <p>Common or very common Depression (sometimes severe); headache; nausea</p> <p>Frequency not known Vomiting</p>
Records to be kept	<p>The following should be recorded in client's notes on PharmOutcomes:</p> <ul style="list-style-type: none"> • 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
- Weight if above 70kg or BMI over 26kg/m²
- Date and time of supply
- Dose given (Levonorgestrel tablet 1.5mg x 1 tablet)
- Batch number and expiry date of tablet
- Advice given and leaflets supplied
- Name of pharmacist who supplied the medication
- Known EHC failure after levonorgestrel 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.

PGD

Client information

<p>Written information to be offered to client (optional/back up)</p>	<p>Patient Information Leaflet covering:</p> <ul style="list-style-type: none"> • The importance of taking the dose of LNG-EHC as soon as possible after supply • If vomiting occurs within 3 hours of taking LNG-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 in particular that LNG-EHC is not 100% effective: <ul style="list-style-type: none"> ○ 95% if taken within 24 hours of UPSI ○ 85% if taken after 25-48 hours ○ 58% if taken after 49-72 hours ○ Unknown if after 72 hours
<p>Verbal follow-up advice to be given to client</p>	<ul style="list-style-type: none"> • Higher weight (>70kg) or BMI (>26kg/m²) could reduce the effectiveness of EHC. • If vomiting occurs within 3 hours of taking LNG-EHC a replacement dose should be taken immediately. • Discuss STI risk and refer to sexual health service, if necessary. • Offer supply of free condoms. • The patient should report any unusual cramping pain or vaginal bleeding. • 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 ongoing contraception and how to access this. • Contraception may be started immediately after LNG-EHC. • Stress the need for reliable contraception for the remainder of cycle and in the future.

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) On-Line: <https://bnf.nice.org.uk/drug/levonorgestrel.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 Levonorgestrel <https://www.medicines.org.uk/emc/product/8626>
7. EMC PIL Levonorgestrel <https://www.medicines.org.uk/emc/product/8626/pil>

Appendix 2

Pharmacist Payment

	PharmOutcomes
Pharmacist Clinical Consultation	£ (VAT except)
EHC supplied - Levonorgestrel 1.5mg 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:

The group direction is to be read, agreed to, and signed by all staff it applies to. One copy is to be given to the health professional, another kept in the department.

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:	Date:
Organisation:	
Address:	Telephone Number:



Appendix 6



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

