ISLE of WIGHT COUNCIL

NHS
Isle of Wight Clinical Commissioning Group

PATIENT GROUP DIRECTION

The supply of

Levonorgestrel 1500mcg tablet

by registered Accredited Community Pharmacists for

For Emergency Hormone Contraception (EHC)

In Community Pharmacy for Isle of Wight NHS 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: 5

Change history

Version number	Change details	Date
v1	Draft reformatted to standard template format	29/4/14
v5	Final amendments following review by Public Health and Community Pharmacy	21/11/14

PGD approval date/ Valid from:	**1/4/15**
Local authority implementation date:	**1/4/15**
Local authority signature:	(DPH LA)
Review date:	**1/4/17**
Expiry date:	**1/4/17**

NHS
Isle of Wight

PGD Ref No. – EHC1.5

PGD Accountability Record

PGD Development Group

Name	Job title and organisation	Signature	Date
Beth Shaw	Lead author – Medicines Management Pharmacist CCG		26/11/15.
Dr David Turner	Lead doctor		30.1.15
Paul Jerram	Lead pharmacist – Head of Medicines Management CCG		5/2/15
Teresa Day	Medicines Management Nurse Lead		17/3/15
Lauren Stott	Public Health Development Commissioner	Lauren Stott	6/3/15
Kevin Noble	Pharmacist Representative		

PGD Authorisation

This PGD has been approved and authorised for use by:

Commissioning organisation

Name	Authorising Professional	Signature	Date
Dr John Rivers	CCG Executive Chair & Clinical Lead		20/2/15
~~Karen Morgan~~ Loretta Kunsella	CCG Quality and Patient Safety Lead Director of Quality & Clinical Services		24/2/15
Mr Paul Jerram	CCG Prescribing/ Pharmacist Lead		5/2/15
Dr Rida Elkheir	A Director of Public Health		26/3/15

Provider Organisation (adoption if needed)

	Name	Authorising Professional	Signature	Date
For Pharmacy Company employed staff only:		Manager of healthcare professional		
For Primary Care Practice staff only:		GP/ Authorising professional		

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

Initial training	• Understanding what a PGD is and how to work under a PGD
	  • GPhC codes of Professional Conduct
	  • Legal framework of PGD's
	  • Medicine, Ethics and practice – Royal Pharmaceutical Society
	• Completion of CPPE distance learning on emergency contraception.
	• Understanding of the Fraser Guidelines for talking to under 16's about contraception
	• Understand local policies of documentation for assessing under 16's suitability for EHC under the Fraser Gudielines

Competency assessment	Certificate of completion of CPPE training programme:
	  • CPPE Emergency Contraception certificate (e-assessment)
	  • CPPE Contraception certificate (e-assessment)
	  • CPPE Safeguarding children and vulnerable adults certificate (e-assessment)

Additional requirements	• Access to supplies of Levonorgestrel 1500mcg Tablets • Access to British National Formulary • Organisational policy on operating under PGD's
Ongoing training and competency	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

Retain a copy of each version of the Patient Group Direction for ten years. A copy of this PGD should be given to the CCG, Public Health at IOW council, the healthcare professional(s) listed above, their manager(s) and the original is to be retained by the Prescribing Advisor/ 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

Clinical condition or situation to which this PGD applies	A female requesting emergency hormonal contraception (EHC) To provide oral hormonal emergency contraception to female clients: • Aged 13 years and over, who present in person at the Pharmacy • To prevent an unwanted pregnancy following Unprotected Sexual Intercourse (UPSI) within 72 hours. • Request it within 72 hours following unprotected sexual intercourse (UPSI)
Inclusion criteria	• Any female aged 13 years or over requesting EHC within 72 hours of unprotected sexual intercourse (UPSI) after an episode of unprotected sexual intercourse (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 previously presenting for EHC who has vomited within 3 hours of taking a dose of EHC and is still within the 72 hours of UPSI • Informed consent has been given • For Clients aged under 16 the conditions of the Fraser Guidelines must be understood and met
Exclusion criteria	Absolute contraindications to use: • 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 • Unexplained vaginal bleeding Special considerations where the use of an IUD may be more appropriate. • Liver disease • UPSI of more than 72 hours • Enzyme inducers: 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, as listed in the BNF, especially remedies containing St John's Wort, (Hypericum perforatum millepertuis) • Severe malabsorption conditions i.e. Crohn's disease. • Hypersensitivity to any of the ingredients in the preparation (see product insert). • Previous history of salpingitis or ectopic pregnancy
Cautions (including any relevant action to be taken)	**Pregnancy** Levonorgestrel should not be given to pregnant women. It will not interrupt a pregnancy. In the case of continued pregnancy, limited epidemiological data indicate no adverse effects on the fetus but there are no clinical data on the potential consequences if doses greater than 1.5 mg of levonorgestrel are taken (see section 5.3.). **Breast-feeding** Levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding female takes the tablet immediately after feeding and avoids nursing at least 8 hours following levonorgestrel administration. **Fertility** Levonorgestrel increases the possibility of cycle disturbances which can sometimes lead to earlier or later ovulation date. These changes can result in modified fertility date, however, there are no fertility data in the long term.
Arrangements for referral for medical advice	• 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 IOW NHS Trust through PharmOutcomes if client consents. If client does not consent client can still access EHC.
Action to be taken if patient excluded	• 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. • Supply condoms and counsel on alternative methods of contraception available.
Action to be taken if patient declines treatment	• 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 • Supply 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 *Include ▼ for black triangle medicines*	Levonorgestrel 1500mcg tablet
BNF Chapter Category	7.3.5
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.
Adverse events and side effects	Please refer to most current BNF for full details. Mostly well tolerated, but some clients may experience: - Nausea (25%) - Vomiting (5%) - Breast tenderness (10%) - Temporary disturbance of menstrual cycle i.e. bleeding, spotting, delayed or early next period (13%) - Headache, dizziness &/or fatigue (10-17%) - Abdominal pain - Bleeding (not related to menses) Female must be counselled on these events and how best to manage them. A female presenting with any rarer or more severe side effects must be referred to their GP for review and assessment

	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. -
Records to be kept	The following should be recorded in client's notes on PharmOutcomes: • Patient's name address, date of birth and 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 • Date and time of supply • Dose given • Batch number and expiry date of tablet(s) • Advice given and leaflets supplied • Signature, printed name and designation of nurse who supplied the medication • Known EC 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.

Client information

Written information to be given to client	• The importance of taking the dose of levonorgestrel as soon as possible after supply
	• 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 Levonorgestrel is not 100% effective:
	  • 95% if taken within 24 hours,
	  • 85% if taken 25-48 hours
	  • 58% if taken 49-72 hours
	  • Unknown if after 72 hours
	• Provide FPA leaflet on emergency contraception
	• Cu-IUD failure rate is considerably less than 1% (2), and may be removed 3-6 weeks after insertion
	• Stress the need for reliable contraception for the remainder of cycle and in the future
	• What to do if patient vomits within 3 hours (per local protocol)
	• Discuss STI risk and refer to sexual health service, if necessary.
	• Advise on STI avoidance - Emphasizing that EHC does not offer any protection against sexually transmitted infections and that condoms are the only means of contraception that also provide protection against these. Offer supply of free condoms.

Follow-up advice to be given to client	• Advise to attend sexual health service for follow up if required for a pregnancy test, STI screening, contraception or if any concerns with contraception. • If the patient vomits within 3 hours of taking the tablet she should return for a further dose to be supplied as long as the second dose still falls within the 72-hour limit. • The patient should report any unusual cramping pain or vaginal bleeding. • Seek advice if period is more than 5 days late, if there is lower abdominal pain or if the period is abnormal in any way.

Healthcare professionals' agreement to practise

Agreement by Registered Pharmacist(s) within.....(*company name*) to administer Levonorgestrel in accordance with the Levonorgestrel 1500mcg tablet for Emergency Hormone Contraception Patient Group Direction (PGD)

I hereby confirm that I have read the above PGD and its supporting documents. I have the appropriate training and competency to safely carry out the procedures and practices mentioned above and I agree to supply the medicine in accordance with this directive:

Name	Position; Qualifications and professional registration number	Signature	Date	Reaccreditation Date	Name of Senior representative of company authorising Pharmacist	Signature	Date

Business address Of Pharmacy operating Under PGD: _____

Appendix A

Key References

1. Summary of Product Characteristics – Levonoregestrel 1500mcg
2. British National Formulary (BNF)
3. General Pharmaceutical Council (GPhC) - Codes of Professional Conduct
4. Royal Pharmaceutical Society (RPSGB) - Medicines, Ethics and Practice (*most up-to-date version)*
5. CPPE Training package on Emergency Contraception
6. Emergency Contraception: Clinical Effectiveness Unit (updated January 2012) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf
7. Fraser Guidelines and Gillick competence DOH
8. NICE Good Practice Guidance 2 – Patient Group Directions. Aug 2013
9. NICE Good Practice Guidance 2 – PGDs' competency frameworks. Jan 2014
10. NICE Public Health Guidance 51 – Contraceptive Services with a focus on young people up to the age of 25 (Issued: March 2014)

Appendix 2

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.