Version 2 – October 2017

Milton Keynes Public Health EHC Pharmacy Supply Scheme

LEVONORGESTREL

PATIENT GROUP DIRECTION

For the supply of Levonorgestrel as Emergency Hormonal Contraception (EHC) by Registered Pharmacists

Issue date: 1st October 2017

Expiry date: 30th September 2019

Review date: 1st August 2019

Definition of clinical condition/situation	A female who has had Unprotected Sexual Intercourse (UPSI)within the past 72 hours

Inclusion criteria for treatment according to this Patient Group Direction	Any female aged 13 and over and under 25, who attends a participating pharmacy and requests EHC who has had • UPSI within the last 72 hours ***OR*** • a contraceptive method failure, of any sort, within the last 72 hours ***AND*** • have chosen Levonorgestret oral EHC after explanation of the intrauterine option and if the alternative oral preparation (Ulipristal) is contraindicated or less suitable NB – supply may be made to a woman refusing to divulge her age or over 25, at the discretion of the pharmacist when in the best interests of that individual

Exclusion criteria preventing treatment according to this Patient Group Direction	**Absolute contraindications to use:** • Hypersensitivity to any of the ingredients in the preparation (see product insert) • Aged under 13 years (refer to Brook) • Aged between 13 and 16 years but not Fraser competent (refer to Brook) • Aged over 25 (refer to Brook) • Known or suspected pregnancy, including previous, untreated, UPSI in same cycle that occurred more than 72 hours previously • Levonorgestrel taken within the previous 12 hours (refer to Brook) • Less than 21 days post-partum • Unexplained vaginal bleeding • Galactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption • Current Ciclosporin use **Circumstances which exclude Levonorgestrel use but where an intrauterine contraceptive device (IUD) or Ulipristal may be more appropriate** ➢ UPSI more than 72 hours before decision to take EHC (refer to Brook) ➢ Severe malabsorption conditions e.g. active Crohn's disease ➢ Taking liver enzyme inducing drugs or other products (see current FFPRHC website for list if necessary) ➢ Active acute Porphyria ➢ Liver disease with unclear diagnosis ➢ Other medical condition(s) that make a definitive decision impossible

Action to be taken when a client is excluded from treatment according to this Patient Group Direction	• Re-emphasise the possibility of an intrauterine contraceptive device (IUD) as alternative • Signpost immediately to another local service eg Brook, their own GP or Urgent Care Service (UCS) – provide phone numbers and impress upon them the need for urgency

	• Record reason on Client Record form, and electronic record if appropriate. In particular, document any refusal of treatment or exclusion due to Safeguarding issues • If Child Protection/Safeguarding of children or vulnerable adult issues are encountered, the relevant local protocol must be followed – Under 13s and those 13-16 who are not Fraser competent should be referred to Social Services for safeguarding and to Brook for their contraceptive needs • In cases of suspected rape or sexual assault, refer to Sexual Assault Referral Service – locally called SOLACE

Description of treatment available under this patient group direction

Name of drug to be issued	Levonorgestrel

Name of product to be administered	Levonorgestrel 1500microgram tablet - this includes any generic or branded product as specified by the commissioners If not to be taken at the time of the consultation, packs must be labelled with • Patient's name and date • Pharmacy name/address/phone • 'Keep Out of Reach of Children' • 'Follow enclosed instructions'

Legal status	Prescription Only Medicine (POM)

Dose to be administered – NB must be issued directly to client by the authorised pharmacist only and cannot be delegated	1500 micrograms (one tablet) as a single dose

	Note: For clients with a BMI > 26 or who weigh more than 70kg or are taking Cytochrome p450 liver enzyme inducers, including herbal remedies eg St John's Wort, and who refuse to contemplate IUD use, double the dose i.e. 3000 micrograms as a single dose - Unlicensed dose but supported by FRSH – advise women accordingly
Route of administration	Oral
Frequency of administration	Single dose only but see below If client vomits within 3 hours** of taking Levonorgestrel, repeat the dose taken. If client vomits again within a further 2 hours, do not give any further dose and refer to a doctor Notes: - can be used more than once in the menstrual cycle if clinically indicated but not under this PGD unless as above
Timing of administration	To be taken as soon as possible – must be no later than 72 hours after UPSI
Maximum dosage for pharmacist administration	1500 micrograms per dose unless the criteria dictate a doubled dose of 3000 micrograms (2 tablets) per dose - a 1500microgram dose may be repeated if vomiting occurs as above
Common side effects	Please refer to SPC or current BNF for full details - Mostly well tolerated, but some clients may experience: • Nausea • Vomiting • Breast tenderness • Temporary disturbance of menstrual cycle ie bleeding, spotting, delayed or early next period • Headache, dizziness and/or fatigue
Interactions	• Cytochrome p450 liver enzyme inducers, including herbal remedies eg St John's Wort – also ***see Dose to be administered, above***

	• Anticoagulant drugs phenindione and warfarin (may alter anticoagulant effect) – advise client to monitor INR within 3 days – facilitate the arrangement of an INR blood test appointment during consultation if possible – document advice to see own GP if not possible

Client advice re medication	• Discuss options, including benefits, effects and alternatives, including IUD use, the latter being a more effective treatment (100% v 84%) – the difference being greater when taking enzyme inducers • Discuss that levonorgestrel efficacy decreases with time and that Ulipristal may be a more effective option • Explain that Mirena and Jaydess are Intrauterine Systems (IUS), not IUDs, and are not suitable for post coital Emergency Contraception • Reassure that there is no evidence of abnormalities or complications if a pregnancy goes to term after EHC use • There is no reason to stop breastfeeding • Explain possible altered bleeding pattern following use and that Levonorgestrel is not 100% effective so a pregnancy test should be performed if the next period is 5-7 days late or bleeding is lighter than usual • If pregnancy occurs, contact GP or other professional eg Brook • Discuss STI risk and condom use. • Provide the Patient Information Leaflet • Discuss need for reliable barrier contraception for the remainder of cycle for maximum efficacy and the need to plan contraception and STI protection for the future – refer on to Brook or GP • Return for repeat dose if vomits within 3 hours of taking Levonorgestrel 1500mg • Seek medical advice urgently if lower abdominal pain develops (ectopic risk) • If vomiting occurs within 3 hours a second dose will be required so she should return to the pharmacy or contact Brook

Follow up advice	Advise the client to see a doctor if period is more than 7 days late or if the period is unusual in any way, eg lighter than normal. Client should see a doctor immediately if she experiences pain (especially if on one side and severe), pain under the ribs or in the shoulders, fainting or feeling light-headed.
Identification, management and reporting procedure of adverse reactions	Use the yellow card at the rear of the BNF or go to www.yellowcard.gov.uk for reporting any adverse reactions. Anyone, including the client, can report.

Recording	The following should be recorded on the client's record form, using black ink (in addition to PMR entries) - Date of consultation - Date of LMP/bleeding pattern - Dates of all UPSI since last period - Day of cycle when current episode of UPSI occurred - Relevant PMH - Medication history - Current contraceptive method - Any discussion with named doctors - Advice given/leaflets provided - Future contraceptive plan - Product name and batch number - Indications for use - Date, time, dose & frequency of administration - Note if unlicensed use due to double dose or extra dose given post vomiting - Actions taken following administration - Unexpected occurrences (report to GP) - Signature (if paper based), printed name, qualification and registration of pharmacist - 'Supply/administration made under Levonorgestrel PGD 2017' - Name of agency/individual contacted if onward referral made

References and other source material:

1. Faculty of Sexual & Reproductive Health Care (2016). UK Medical Eligibility Criteria for Contraceptive Use. London https://www.fsrh.org/ukmec/
2. Emergency Contraception , Faculty of Family Planning and Reproductive Health Care Guidance, Clinical Effectiveness Unit 2017 https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/
3. http://emc.medicines.org.uk/ (SPCs)
4. Royal Pharmaceutical Society of Great Britain. *British National Formulary* (latest edition). British Medical Association. London
5. Medicines, Ethics and Practice – latest edition
6. NICE Guidance PGDs https://www.nice.org.uk/Guidance/MPG2

Characteristics of staff authorised to take responsibility for the supply or administration of medicines under this patient group direction

Professional and other qualification required	• Current GPhC Registration • Working within a participating pharmacy • Authorised by a contractor to deliver the Local Enhanced Scheme (LES) – the contractor is responsible for ensuring that the pharmacist fulfils the eligibility criteria • Authorised by MK Council Public Health to work with this PGD • Current Enhanced DBS Certificate • Have attended the CPPE Emergency Contraception workshop within 3 years of starting the service and then attend a workshop every 3 years as a refresher • Have read the latest FRSH guidance on Emergency Contraception
Specialist qualification or experience required	- Pharmacological knowledge relating to the medicine used and its dosage - Attendance at/completion of prescribed training events or packages - Regular approved resuscitation training – usually annual or as determined by the commissioners - Competence in assessing the capacity of a client to give informed consent
Requirement of education/training	Evidence of continued individual competence, as shown by completion of the CPPE Declaration of Competence for Emergency Contraception within the past 3 years - this will include successful completion of the CPPE online assessments associated with the e-learning for Contraception, Emergency Contraception and Safeguarding of Children and Vulnerable Adults within 3 years

Management and monitoring of this patient group direction

Professionals responsible for drawing up and reviewing this patient group direction	Name: Dr Hayley Jenkins Family Planning/Contraception Doctor Signature  **4/10/17** Name: Ross Lynton Groves FRPharmS Consultant Pharmacist Signature: 4/10/17
Signed on behalf of Milton Keynes Council (the authorising body with which a contract or agreement for the provision of these services has been made)	Dr Dyna Arhin Consultant in Public Health Medicine Signature:  4/10/17
Signed on behalf of the Contractor authorising the use of this patient group direction in their pharmacy/pharmacies	Name/Position: Signature: **Date :-**

Pharmacy Name :-

Pharmacy address:-

Pharmacy Contract Number :-

NB – the original of this document must be kept in the pharmacy to which it relates at all times

I confirm that I have read and understood the content of this patient group direction and that I have received the appropriate training in order to implement it effectively

I declare that I am competent to understand and/or identify and/or advise on

- **The clinical situation covered by this PGD**
- **The medicine to be supplied or administered under this PGD**
- **The relevant sections of Medicines, Ethics and Practice that relate to this PGD**
- **Working under a PGD when supplying or administering medicines including the need to sign the relevant document in every participating pharmacy in which I provide services**

Date	Name and role - e.g. Regular pharmacist, locum etc (print)	Signature

Audit and ongoing monitoring of this patient group direction

Audit should take place at regular intervals and within six months of the implementation of this PGD to ensure good practice. Pharmacist should adhere to this PGD without exception. The audit can be by a designated pharmacist or service manager and the results fed back in a safe environment. It is vital to audit specific areas of practice. These should include:

Were all the entries correctly recorded? Yes/No
Were there any contraindications to the use of Levonorgestrel? Yes/No
If yes was the woman referred elsewhere? Yes/No
If < 16 years was she assessed competent to consent to treatment? Yes/No
Was the assessment recorded according to policy? Yes/No
Was any refusal of treatment recorded? Yes/No
Was the name of the medication stated clearly, together with the following?

- Date and time? Yes/No
- Dose of medication? Yes/No
- Route of administration? Yes/No
- Pharmacist's name and signature? Yes/No
- Pharmacist's designation? Yes/No
- Follow-up advice? Yes/No

This list is not exclusive and other aspects of care could be audited at the same time. Local group audits should be used in preference when available and audit performed at the request of the commissioning or other local body

Relevant Local Organisations for advice or referral

Brook – exclusion from PGD (age, time limit, alternative method chosen, STI etc)

Milton Keynes Public Health

Social Services – Child Protection, Safeguarding etc

Sexual Assault Referral Service – Rape or other assault
SOLACE 24 hour number **0300 130 3036** – Sherwood Drive, Bletchley, Milton Keynes, MK3 6TP

Local GP Practices