Community Pharmacy Emergency Hormonal Contraception Service

Patient Group Direction (PGD) for the supply of Levonorgestrel 1.5mg Tablet Emergency Hormonal Contraception (EHC) by registered Community Pharmacists in Wigan Borough

Staff/Premises Requirements	
Staff characteristics	**The Community Pharmacist must be authorised by name as an approved practitioner under the current version of this PGD before working to it. Please use the signature sheet at the back of this document.** Pharmacist registered with the General Pharmaceutical Council who: • Has completed and signed a Declaration of Competence (DoC) for the supply of Emergency Hormonal Contraception (EHC) including appropriate safeguarding training and training in the use of PGDs. A copy of the DoC should be kept with the current PGD within the Pharmacy. • Is able to demonstrate they have achieved the competency levels specified in the NICE competency Framework for Health Professionals using Patient Group Directions. https://www.nice.org.uk/guidance/mpg2/resources • Follows guidelines set out by the General Pharmaceutical Council and follows the professional standards issued by this body. • Is aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual Pharmacist to keep up-to-date with continuing professional development in the field of emergency contraception. • Attends updates on medicines supplied/administered under Patient Group Directions or on the Community Pharmacy Emergency Hormonal Contraception Service as required by Wigan Council. • Is working in suitable premises.
Premises characteristics	Community Pharmacy with a contract with Wigan Council for the provision of Emergency Hormonal Contraception within Wigan Borough. Has a suitable area for a confidential consultation.
Continued training requirements	• Pharmacists must maintain their own level of competence, updating with evidence of Continued Professional Development (CPD). • The Declaration of Competence should be reviewed and updated at least once every 3 years or if there is a significant update in guidance. • Pharmacists should be constantly alert to any subsequent recommendations from the Department of Health and other sources of medicines information (e.g. Faculty of Sexual and Reproductive Healthcare Clinical Guidance).

Clinical Condition or situation to which this PGD applies	
Indication	Prevention of pregnancy from unprotected sexual intercourse (UPSI) or failure of a contraceptive method.
Inclusion criteria	• Women with spontaneous menstrual cycles (onset of menarche) presenting within 72 hours of UPSI or failure or reduced efficacy of a contraceptive method (including condom failure, severe vomiting/diarrhoea whilst on oral hormonal contraception) requiring emergency contraception with Levonorgestrel and where the client and pharmacist have agreed levonorgestrel is the most appropriate form of emergency contraception in line with the service specification (refer to https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/) • Women who have vomited within 3 hours of taking Levonorgestrel 1.5mg tablet for emergency contraception as long as the replacement dose is within 72 hrs after UPSI. • Women who cannot be reassured that they are not at risk that contraception was not used correctly. • Informed consent has been given for the supply of the medicine. • Young persons under the age of 16 years must be competent under the Lord Fraser Guidelines (or have treatment consent from a carer with parental responsibility). • If the client's menstrual period is delayed by more than 5 days from the expected date the client must have a pregnancy test and a negative result before inclusion. • If the client's last period was abnormal in any way the client must have a pregnancy test and a negative result before inclusion. • If a woman requiring oral emergency contraception for UPSI in the last 72 hours has also had (or may also have had) UPSI more than 21 days ago AND has not had a normal menstrual period since the earlier UPSI, the client must have a high-sensitivity urine pregnancy test and a negative result before inclusion • If appropriate, clients can take more than one dose of Levonorgestrel within the same menstrual cycle but they must be advised about possible cycle disruption.
Exclusion criteria[1]	• Women under age of menarche • Informed consent has NOT been given for the supply of the medicine • Clients under the age of 16 years and assessed as not competent using the client competence form (based on Lord Fraser Guideline) and no parent/guardian consent. • UPSI more than 72 hours ago. Consider provision of Ulipristal in line with the service specification if UPSI was within 120 hours. • Known allergy or hypersensitivity to Levonorgestrel or any ingredient contained in the product.

[1] Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it would be outside the remit of the PGD. Patients should be referred to sexual health services.

	• Known or suspected pregnancy (exclude suspected pregnancy using a pregnancy test). • Less than 21 days post partum • Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease • Unexplained or unusual vaginal bleeding. • Severe liver disease. • Severe intestinal malabsorption syndromes, eg Crohn's Disease. • Hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. • Active acute porphyria. • Active trophoblastic disease. • Previous ectopic pregnancy • Previous history of salpingitis (inflammation/infection of the fallopian tubes) • Patients taking Ciclosporin as Levonorgestrel may increase the risk of Ciclosporin toxicity • Less than 5 days following ingestion of Ulipristal emergency contraception (UPA-EC)
Special Considerations/Unlicensed Use	**If under 13 follow local safeguarding policy.** **For young people under the age of 16 and vulnerable young people under the age of 19, consider referral to safeguarding as required.** Women using enzyme inducing drugs and for four weeks after stopping them, including herbal remedies containing St John's Wort, should be advised that a copper IUD is the preferred option for emergency contraception. However, if this is declined, a double dose of Levonorgestrel (3mg) can be offered. Refer to dosage section. FSRH advises that the effectiveness of Levonorgestrel could be reduced if a woman has a BMI >26 kg/m^2 or weight >70 kg. It is recommended that either Ulipristal or a double dose (3 mg) of Levonorgestrel is given in this situation. It is unknown which is more effective. If a double dose of Levonorgestrel is provided the client must be informed that this is unlicensed.
Management of excluded patients	Consider provision of Ulipristal in line with the product licence under the pharmacy service if appropriate and within 120 hours of UPSI. Discuss alternatives and refer to a doctor or sexual health service. Record the reason for exclusion and all action taken/advice given on the Client Record Form.
Management of patients not wishing to receive care under this PGD	Advise client of alternative sources of treatment and refer/signpost to doctor or sexual health service. Advise client of possible consequences of refusing treatment Document the refusal and advice given on the Client Record Form.

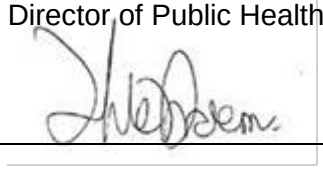
Drug Details	
Name, form & strength of medication	Levonorgestrel 1.5 mg tablet
Legal classification	Prescription Only Medicine (POM).
Route/Method	Oral
Dosage	One 1.5mg tablet to be taken as soon as possible, preferably within 12 hours and no later than 72 hours, after unprotected sexual intercourse. Ideally the tablet should be taken in the Pharmacy. In exceptional circumstances the client can take the tablet home to take at an agreed time. In this case be aware of the possibility of the 'client' being a third party. **Enzyme inducing drugs** Women who have used CYP3A4 enzyme inducing medicines or herbal products within the last 4 weeks should be recommended to use a non-hormonal emergency contraception, i.e. copper intrauterine device (Cu-IUD) if appropriate. For women unable or unwilling to use Cu-IUD a double dose of levonorgestrel (2 x 1.5mg tablets taken together) should be offered but women should be informed that the effectiveness of this regimen is unknown. **BMI >26 kg/m^2 or weighing >70 kg** Women with BMI >26 kg/m^2 or weighing >70 kg should be advised that the effectiveness of the Cu-IUD is not known to be affected by weight or BMI. For women unable or unwilling to use a Cu-IUD or Ulipristal then a double dose of Levonorgestrel (2 x 1.5mg tablets taken together) should be offered and the patient advised that this is unlicensed.
Frequency	Single dose treatment.
Duration of treatment	Single dose treatment. If the client vomits within 3 hours of taking the dose, a replacement supply should be made provided that the replacement dose remains within 72 hours of the episode of UPSI.
Maximum or minimum treatment period	Single course of treatment.
Quantity to supply/administer	1 x 1.5mg tablet. 2 x 1.5mg tablets for women taking enzyme-inducing drugs (Appendix 1 BNF) or with BMI >26 kg/m^2 or weighing >70 kg.
Side effects	**Very common (>1in 10)** Nausea, bleeding not related to menses*, abdominal pain, fatigue, headache. **Bleeding patterns may be temporarily disturbed, but most women will have their*

	next menstrual period within 5-7 days of the expected time. **Common (>1/100, <1/10)** Breast tenderness, delay of menses more than 7 days**, irregular menstrual bleeding and spotting, dizziness, vomiting, diarrhoea. ***If the next menstrual period is more than 5 days overdue, pregnancy should be excluded.* For a detailed list of **all** adverse reactions associated with Levonorgestrel refer to the Summary of Product Characteristics for this medicine. http://www.medicines.org.uk/emc/ Healthcare professionals, patients and parents/carers are encouraged to report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk In the event of untoward or unexpected adverse reaction: • Seek appropriate emergency advice and assistance • Inform the client's GP if the client consents to this • Document the adverse reaction in the client's record
Cautions	• Warfarin and other coumarin anticoagulants–anticoagulation affected by Levonorgestrel, advise client to have an early INR check. • If the client is taking any concomitant medication or treatment it is the pharmacist's responsibility to ensure that treatment with the drug detailed in this PGD is appropriate. In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given. If the requirements of this PGD cannot be complied with the client must be referred. • Lactation – Levonorgestrel is secreted into breast milk. Potential exposure of an infant can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing for at least 8 hours following Levonorgestrel administration. There is no evidence to suggest Levonorgestrel in breast milk has an adverse effect on the infant.
Advice to client / carer	• Women asking for emergency contraception should be informed that a Cu-IUD device is more effective than an oral method (NICE QS129, September 2016). • A Cu-IUD should be recommended to all clients, advice should be provided on how to obtain a Cu-IUD. If a client prefers a Cu-IUD they should still be provided with oral emergency contraception in case the Cu-IUD fitting is not done or proves unsuitable. • Advise women that Ulipristal has been demonstrated to be more effective than Levonorgestrel. • Advise women that the available evidence suggests that oral emergency contraception administered after ovulation is ineffective. • Where appropriate women should be informed that it is possible that higher weight or BMI could reduce the effectiveness of oral

Advice to client/carer cont…	emergency contraception, particularly Levonorgestrel and that the effectiveness of the Cu-IUD is not known to be affected by weight or BMI. • Explain Levonorgestrel treatment, administration and follow up. • Mode of action – thought to inhibit ovulation and fertilisation if intercourse has taken place in the pre-ovulatory phase. • Levonorgestrel is generally well tolerated but all clients must be provided with advice about side effects; in particular advice must be given about vomited tablets, delayed menses and the failure rate. If the client experiences serious side effects after taking the medication they should consult their GP. • If vomiting occurs within 3 hours of taking the tablet a replacement dose must be taken as soon as possible and within 72 hours of UPSI. • Advise that oral emergency contraception will not provide on going protection against pregnancy for the remainder of the cycle and that the client will need to use contraception or abstain from sex to avoid further risk of pregnancy. • Oral emergency contraception is not as effective as using a regular method of contraception. • All clients (including those on hormonal contraception) should be advised that they must use condoms reliably or abstain from intercourse until contraception becomes effective. • Offer all clients a free supply of 3 condoms. • Regular hormonal contraception should be continued. If the client is using hormonal contraception check she has ongoing supplies, knows how to use the medication correctly including any missed dose guidelines. Clients taking the combined oral contraceptive who are in the last 7 days of active tablets must be advised to run two packs together. Advise the client to contact their contraceptive provider for review of method if necessary. • If the client is not using a form of regular contraception advise the client on where to go to get regular contraceptives and advice. • After Levonorgestrel menstrual periods are usually normal and occur at the expected date. They can sometimes occur earlier or later than expected by a few days. Emergency contraception does not prevent pregnancy in every instance. Pregnancy testing is advised if, after oral emergency contraception, the next menstrual period is delayed by more than 7 days, is abnormal or lighter than usual or is associated with abdominal pain that is not typical of the woman's usual dysmenorrhoea a pregnancy test should be carried out. If the client is taking hormonal contraception they should do a pregnancy test in 21 days as they may have a withdrawal bleed despite being pregnant. • If pregnancy occurs after treatment with Levonorgestrel the client needs to see a GP. • If clients experience abdominal pain this could be a sign of ectopic pregnancy, medical advice should be sought. • Oral emergency contraception will not interrupt a pregnancy if taken when already pregnant. Should the client become pregnant following EHC there is no evidence to suggest that taking oral emergency contraception will have harmed the foetus although all

	pregnancies carry some risk of abnormality. • Explain the risk of sexually transmitted infections and advise where testing/treatment can be obtained locally. • Provide contact details for the local sexual health services. • Supply marketing authorisation holder's patient information leaflet (PIL) provided with the product. • Where the product is being used outside of its product licence but is supported by a body of evidence within FRSH guidance, women should be informed of this.
Records and follow up	
Referral arrangements	To appropriate healthcare professional and/or sexual health services as detailed in the service specification.
Records/Audit trail	• All records must be clear, legible and contemporaneous. • The Pharmacist must complete the Client Record Form in full for every consultation to ensure all appropriate data is recorded. • If the client is under 16 years of age the Client Competence Form must also be completed. • These must be stored securely in the Pharmacy where the consultation took place for 8 years in adults, or until 25th birthday if the client is aged less than 18 years of age. • The Pharmacy will complete the EHC invoice/claim form and relevant quality performance backing data regarding Emergency Hormonal Contraception provision as required by Wigan Council and e-mail them to startwellinvoices@wigan.gov.uk
References	
References/Resources	Faculty of Sexual and Reproductive Healthcare Clinical Guidance: Emergency Contraception. Clinical Effectiveness Unit March 2017 (updated December 2017). https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ Accessed June 2019. Summary of Product Characteristics for Levonorgestrel 1.5 mg Tablet. Generics UK T/A Mylan. www.medicines.org.uk. Last updated 30 January 2019. Accessed June 2019 https://www.medicines.org.uk/emc/product/8626/smpc Summary of Product Characteristics for Levonelle® 1500 microgram Tablet. Bayer plc Last updated 21 June 2018. Accessed June 2019 https://www.medicines.org.uk/emc/product/133/smpc British National Formulary (BNF) online. Accessed June 2019. https://www.medicinescomplete.com/#/content/bnf/_686392393 Oral Emergency Contraceptives as Pharmacy Medicines March 2017. Royal Pharmaceutical Society of Great Britain. Accessed June 2019 https://www.rpharms.com/resources/quick-reference-guides/oral-emergency-contraceptives-as-pharmacy-medicines Faculty of Sexual and Reproductive Healthcare Clinical Guidance: Drug

	Interactions with Hormonal Contraception. January 2018. Accessed June 2019 https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ NICE Quality Standard 129 (QS129) Contraception Published September 2016 https://www.nice.org.uk/guidance/qs129/chapter/Quality-statement-2-Emergency-contraception NICE Medicines Practice Guideline (MPG2). Patient Group Directions Published August 2013, Last updated March 2017. https://www.nice.org.uk/Guidance/MPG2/Resources

Authorisation	
Lead Clinician Sexual Health Provider Services for Wigan Council (Clinician is signing to confirm clinical content is accurate and supported by best available evidence)	Name: Dr Indhu Prabakar Position: Senior Clinician Signature:  Date: 10.07.2019
Lead Pharmacist Wigan Borough Clinical Commissioning Group	Name: Linda Scott Position: Director of Clinical Services Signature:  Date: 22.08.19
Authorised by Wigan Council	Name: Professor Kate Ardern Position: Director of Public Health for Wigan Borough Signature:  Date: 22.08.19

This patient group direction must be agreed to and signed by all healthcare professionals involved in its use. The PGD must be easily accessible in the clinical setting.

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their Code of Professional Conduct.

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

Name	**Signature and Date**

Master copy to be retained within the pharmacy premises and available for inspection.