



This Patient Group Direction (PGD) must only be used by registered pharmacists who have been named and authorized by their organization to practice under it. The most recent and in date final signed version of the PGD should be used.




<b>PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OR ADMINISTRATION OF LEVONORGESTREL 1500 MICROGRAMS FOR EMERGENCY CONTRACEPTION BY REGISTERED PHARMACISTS</b>		<b>PoM</b>
	2019.1.BHR.1	

<b>CLASSIFICATION OF DOCUMENT:</b>	Patient Group Direction
<b>PURPOSE:</b>	Supply/administration of Levonorgestrel 1500 microgram tablet to clients without a prescription under a PGD.
<b>Other relevant documents</b>	This PGD should be used in conjunction with Local Enhanced Services Contract and Service Level Agreement. Eligibility criteria may vary between boroughs.
<b>Document Number:</b>	1
<b>Version Number:</b>	4.0
<b>Controlled Document Sponsor:</b>	Directors of Public Health Barking & Dagenham, Havering and Redbridge
<b>Controlled Document Lead:</b>	Lead Consultant Barts Health Sexual Health Primary Care Support Team
<b>Approved By:</b>	
<b>On:</b>	May 31 2019
<b>Review Date:</b>	Nov 30 2021 (sooner if guidelines change)
<b>Expiry Date:</b>	May 31 2022



<p><b>Distribution:</b></p> <p><b>Essential Reading for:</b></p> <p><b>Information for:</b></p>	<p>All registered practitioners supplying or administering Levonorgestrel against this PGD.</p> <p>Sexual Health Commissioners in Barking &amp; Dagenham, Havering and Redbridge.</p> <p>Barts Health Sexual Health Primary Care Support Team.</p> <p>Clinical lead, Integrated Sexual Health &amp; HIV  Women &amp; Child Health Division, Barking, Havering and Redbridge University Hospitals NHS Trust.</p>
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<b>PGD written by:</b>		
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Name	Job title and organization	Signature	Date
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Name	Job title, position and organisation
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## Authorisation

**Organizational  
authorisation – Director of  
Public Health, London  
Borough of Barking &  
Dagenham**

Name: Matthew Cole

Signature:



Date: 29th October 2019

<b>Pharmacy to which the PGD applies.</b>	Pharmacies offering supply of Levonorgestrel under contract to Public Health for Sexual Health Services in Barking & Dagenham, Havering and Redbridge.
<b>Description of the medication to which the direction applies.</b>	Levonorgestrel 1500 microgram tablet.
<b>Legal Category</b>	Prescription Only (PoM).
<b>Off Label use</b>	<ul style="list-style-type: none"><li>• Double dose for women using Liver enzyme inducers.</li><li>• Double dose for women weighing over 70kg or BMI over 26kg/m<sup>2</sup>.</li><li>• Use more than once per menstrual cycle.</li></ul> <p>As per FSRH CEU Guidelines.</p>
<b>Group of professional staff who are authorised to administer/supply under this PGD.</b>	Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC), who are working in a pharmacy contracted to NHS England (London) and providing the service under contract to Public Health for Sexual Health Services in Barking & Dagenham, Havering and Redbridge who have and have completed approved training.

<p><b>Training and method of assessment of competence.</b></p>	<p>Registered Pharmacists must have accessed and completed training approved by Barts Health Sexual Health Primary Care Support Team.</p> <ul style="list-style-type: none"><li>Registered Pharmacists must have accessed and completed training approved by Train All East, Barts Sexual Health Primary Care Support Team</li><li>This mandatory training consists of:<ul style="list-style-type: none"><li>CPPE Emergency Contraception e-Learning Programme (3 Hours).</li><li>CPPE Safeguarding Children Open Learning Programme (1.5 Hours).</li><li>CPPE Contraception Open Learning Programme (12 Hours).</li><li>Local EHC PGD training (webinar and / or face to face training) including a pass in the quiz.</li></ul></li></ul> <p><b><u>Continued professional development</u></b></p> <p>Registered Pharmacists must access regular (at least every 3 years) updates approved of provided by the relevant commissioners.</p> <p>In addition the Registered Pharmacist has the responsibility to update their own DoC every 3 years.</p>
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<b>Clinical situation to which this direction applies.</b>	For women aged from 13 years to 25 years, within 72 hours following unprotected sexual intercourse (UPSI) or contraceptive method failure with the intention of preventing an unintended pregnancy.
<b>Additional Criteria to confirm applicability.</b>	<ul style="list-style-type: none"><li>• All clients must be informed that an intra-uterine device (IUD) (Copper coil) would be the most effective method of emergency contraception. They will be directed to Outpatients East, Barking Community Hospital, Upney Lane, IG11 9LX. BHRUT. Tel no 020 8924 6674 or 020 8924 6563 if they wish to pursue this option.<ul style="list-style-type: none"><li>○ Levonorgestrel should still be given.</li></ul></li><li>• All clients must be informed that Ulipristal acetate (UPA) has been shown to be a more effective method of emergency contraception in some circumstances. UPA should therefore be considered as 1<sup>st</sup> line oral emergency contraception (see UPA PGD).</li><li>• Can be used more than once in the same cycle or can be used for a recent episode of UPSI even if there has been an earlier episode of UPSI outside the treatment window (&gt;72hrs) This is outside the terms of the product license but in line with national guidance. <sup>2</sup></li></ul>

<p><b>Exclusion criteria</b></p>	<p>UKMEC advises that there are no medical contraindications to the use of hormonal EC.</p> <ul style="list-style-type: none"> <li>• Age: under 13 years or over 25 years of age.</li> <li>• Clients aged under 16 if not Fraser Competent.</li> <li>• Pregnant.</li> <li>• Any known hypersensitivity to Levonorgestrel or other ingredients of product used.</li> <li>• More than 72 hours since UPSI.</li> </ul> <p>If the client is receiving any concomitant medication or treatment it is the responsibility of the Registered Pharmacist to ensure that treatment with the drug detailed in this PGD is appropriate. In case of any further doubt advice must be sought from an appropriate health professional and documented.</p>
<p><b>Cautions:</b></p>	<ul style="list-style-type: none"> <li>• Current interacting medication – e.g. St John’s Wort, hepatic enzyme inducers consider double dose (3000mcg as a single dose) or offer Cu-IUD, (see current British National Formulary (BNF) and latest guidance for full list)</li> <li>• Weight: The efficacy of Levonorgestrel 1500 microgram as emergency contraception is reduced in women weighing over 70kg or BMI over 26kg/m<sup>2</sup>. UPA-EC should be considered in this situation. If UPA unsuitable then consider double dose (3000mcg as a single dose) or offer Cu-IUD</li> <li>• Time in menstrual cycle: 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.</li> <li>• Although the available evidence suggests that oral EC administered after ovulation is</li> </ul>



	<p>ineffective, EC should not be withheld for this reason.</p>
<p><b>Action to be taken when a patient is excluded from treatment according to the PGD.</b></p>	<p>The Registered Pharmacist will discuss reasons for exclusion and Outpatients East, Barking Community Hospital, Upney Lane, IG11 9LX. BHRUT. Tel no 020 8924 6674 or 020 8924 6563.</p> <p>Second method of emergency contraception must be discussed and offered if appropriate.</p> <p>Manage safeguarding concerns as per local arrangements.</p> <p>Document action taken.</p>
<p><b>Treatment to be supplied/ administered under the PGD.</b></p>	<ol style="list-style-type: none"> <li>1. Levonorgestrel tablet 1500 micrograms OR</li> <li>2. Levonorgestrel tablets 3000 micrograms (2 x 1500mcg as a single dose) for             <ul style="list-style-type: none"> <li>• those on liver enzyme inducers</li> <li>• or (where UPA-EC inappropriate) wt &gt;70kg</li> </ul> </li> </ol>
<p><b>Security, storage and labelling of medicines.</b></p>	<ul style="list-style-type: none"> <li>• Do not store above 25°C.</li> <li>• If not taken on the premises it must be labelled as per usual labelling requirements for dispensed medicines under the Medicines Act 1968.</li> </ul>
<p><b>Route of administration and method.</b></p>	<p>Oral</p>

<b>Dose to be administered.</b>	1500 micrograms or 3000 micrograms (single dose) To be taken as soon as possible within 72 hours of UPSI.
<b>Frequency of administration.</b>	Single course of one tablet. (or two tablets as per above) Can be used more than once in the cycle if clinically indicated.
<b>Maximum dosage &amp; minimum/maximum period over which the drug may be administered.</b>	One tablet (or two tablets as per above) of Levonorgestrel 1500mcg to be supplied in manufacturer's original pack immediately.
<b>Special considerations/ Additional information</b>	Advice on contraception including LARC and signposting if required:  <b><u>Barking &amp; Dagenham:</u></b> Each client receiving EC or advice via this PGD on the day of treatment will routinely be registered onto the 'Come Correct' C-Card Scheme. This will involve taking and entering the client's details for registration purposes on to an online database, carrying out a condom demonstration, issuing a C-Card wallet with resources and a supply of condoms along with signposting to local contraceptive services / outlets across Barking & Dagenham and London.

<p><b>Warnings &amp; potential adverse reactions.</b></p>	<p>Nausea and Vomiting.          If vomiting occurs within 2 hours of taking the tablet, a repeat dose of Levonorgestrel 1500 should be given.          Other adverse effects include breast tenderness, headaches, dizziness, fatigue.</p> <p>Refer to manufacturer's Product Information leaflet (PIL), and Summary of Product Characteristics (SPC) and current BNF.</p> <p><b>All adverse reactions must be documented and the patient referred to a doctor.          In the event of an adverse reaction follow the incident reporting procedure (see local organizational policy).</b></p> <p>Report serious adverse reactions directly to the MHRA on a yellow card. Yellow cards and guidance on their use are available at the back of the British National Formulary (BNF) or online via the link in eBNF or via the MHRA website <a href="http://www.mhra.gov.uk">www.mhra.gov.uk</a>.</p>
<p><b>Follow up - circumstances under which further advice should be sought and arrangements for referral.</b></p>	<p>The client must be advised to perform a pregnancy test at 3 weeks whether or not they have a period or are on an ongoing method of hormonal contraception.</p> <p>Refer to BHRUT sexual health services as required          Outpatients East, Barking Community Hospital, Upney Lane, IG11 9LX. BHRUT. Tel no 020 8924 6674 or 020 8924 6563.</p> <p>Manage safeguarding concerns as per local safeguarding protocol and service level agreement. This may involve telephoning the local safeguarding team.</p> <p>See:  <a href="http://www.redbridgelscb.org.uk/professionals/">http://www.redbridgelscb.org.uk/professionals/</a>  <a href="http://newsite.bardag-lscb.co.uk/multi-agency-safeguarding-hub-2/">http://newsite.bardag-lscb.co.uk/multi-agency-safeguarding-hub-2/</a>  <a href="https://www.haverling.gov.uk/info/20083/safeguarding_children/412/report_a_concern_with_a_child">https://www.haverling.gov.uk/info/20083/safeguarding_children/412/report_a_concern_with_a_child</a></p>

<p><b>Written or verbal advice to be given to patients or carers before, during or after treatment.</b></p>	<ul style="list-style-type: none"> <li>• EC providers should advise women that the available evidence suggests that oral EC administered after ovulation is ineffective.</li> <li>• No evidence exists that Levonorgestrel 1500 has any teratogenic effect on the fetus. However a normal outcome for any pregnancy that may occur cannot be guaranteed (every woman has 1 in 50 chance of a fetal abnormality).</li> <li>• The next period may be early, on time, or late. If the next menstrual period is more than 7 days overdue pregnancy must be excluded. Instructions must be given to seek medical advice if the next period is exceptionally short or light ( i.e. possible failed treatment).</li> <li>• Levonorgestrel 1500mg is for emergency contraception only. It will not protect against future pregnancy and is not intended to be used as a regular method of contraception due to lack of efficacy.</li> <li>• The manufacturer’s patient information leaflet (PIL) must be handed to the patient.</li> <li>• Seek professional advice if any other abnormal symptoms occur.</li> <li>• Discuss “safer sex” and register with Condom Card scheme.</li> <li>• Patients should be informed that this medicine is being issued under a PGD and is not prescribed.</li> </ul>
<p><b>Record keeping.</b></p>	<p>The Registered Pharmacist must record all significant information accurately and appropriately including assessment of Fraser Competence for clients less than 16 years, including:</p> <ul style="list-style-type: none"> <li>• Complete EHC consultation template as appropriate.</li> <li>• Accurately record consultation outcome.</li> <li>• A record of the drug supplied, batch number and expiry dates must be documented.</li> <li>• The date and time of supply.</li> </ul>

<b>Names of professionals who are authorised to administer/supply drug according to the PGD.</b>	A list of the Registered Pharmacists who have successfully completed PGD training will be kept by Barts Health Sexual Health Primary Care Support Team, BHRUT Sexual Health service and local sexual health commissioners.
<b>Professional with responsibility for ensuring review of the PGD takes place.</b>	A Consultant or the Lead for Barts Health Sexual Health Primary Care Support Team or BHRUT as per contract with relevant commissioners will be responsible for review of the PGD.
<b>Staff responsible for Review of this PGD.</b>	Chair of LPC, North East London Lead for Barts Health Sexual Health Primary Care Support Team or BHRUT as per contract with relevant commissioners

## References

1. \*UK Medical eligibility criteria for contraceptive use UKMEC 2016 <https://www.fsrh.org/ukmec/>
2. Faculty of Sexual and Reproductive Healthcare (2017) Emergency Contraception. Clinical Effectiveness Unit <https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/>
3. Nursing and Midwifery Council (NMC) (2008) Standards for medicine management\_ <http://www.nmc.uk/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf>
4. Nursing and Midwifery Council (NMC) (2008) The code: Standards of conduct, performance and ethics for nurses and midwives <http://www.nmc-uk.org/Documents/Standards/The-code-A4-20100406.pdf>
5. <http://www.nmc-uk.org/Documents/Standards/The-code-A4-20100406.pdf>
6. Nursing and Midwifery Council (NMC) (2009) Record keeping: guidance for nurses and Midwives <http://www.nmc-uk.org/Documents/Guidance/nmcGuidanceRecordKeepingGuidanceforNursesandMidwives.pdf>