



This patient group direction (PGD) must only be used by registered health professionals 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.

## Patient Group Direction (PGD)

For the administration or supply of

**Levonorgestrel 1500 micrograms (1.5mg) single dose**

By registered health care professionals for

**Emergency contraception**

**Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice**

**PGD NUMBER 36**

### 1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021

## 2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

## 3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

## 4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

## 5. PGD adoption by the provider

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job title and organisation	Signature	Date	Applicable or not applicable to area

## 6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
<b>Qualifications and professional registration</b>	<ul style="list-style-type: none"> <li>Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy</li> <li>Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises</li> <li>Specific training in sexual health and/or emergency contraception, or equivalent experience</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria</li> <li>Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD</li> <li>Local training in the use of PGDs</li> <li>Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or advised in the RCN training directory</li> <li>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent</li> </ul>
<b>Competency assessment</b>	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
<b>Ongoing training and competency</b>	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

## 7. Clinical Conditions

<b>Clinical condition or situation to which this PGD applies</b>	<ul style="list-style-type: none"> <li>• To reduce the risk of pregnancy after unprotected sexual intercourse</li> <li>• (UPSI) or regular contraception has been compromised or used incorrectly</li> </ul>
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Any individual presenting for emergency contraception (EC) between 0 and 96 hours following UPSI or when regular contraception has been compromised or used incorrectly</li> <li>• No contraindications to the medication</li> <li>• Informed consent given</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Informed consent not given</li> <li>• Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines</li> <li>• Individuals 16 years of age and over and assessed as lacking capacity to consent</li> <li>• This episode of UPSI occurred more than 96 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 96 hours</li> <li>• Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI)</li> <li>• Less than 21 days after childbirth</li> <li>• Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD)</li> <li>• Known hypersensitivity to the active ingredient or to any component of the product - see <u>Summary of Product Characteristics</u></li> <li>• Use of ulipristal acetate emergency contraception in the previous 5 days</li> </ul>
<b>Cautions (including any relevant action to be taken)</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider</li> <li>• Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Consider ulipristal if the individual presents in the five days leading up to estimated day of ovulation</li> <li>• Levonorgestrel is ineffective if taken after ovulation.</li> <li>• If individual vomits within three hours from ingestion, a repeat dose may be given</li> <li>• Individuals using enzyme-inducing drugs/herbal products or</li> </ul>

<p><b>Cautions (including any relevant action to be taken)</b> (continued)</p>	<p>within 4 weeks of stopping them - see dose frequency section</p> <ul style="list-style-type: none"> <li>• Body Mass Index (BMI) &gt;26kg/m<sup>2</sup> or weight &gt;70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. If levonorgestrel is to be given see dosage section</li> <li>• Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn’s disease. Although the use of levonorgestrel is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed</li> <li>• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented</li> <li>• <b>If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy</b></li> <li>• If the individual has not yet reached menarche consider onward referral for further assessment or investigation</li> </ul>
<p><b>Arrangements for referral for medical advice</b></p>	<p>Patient should be referred to a more experienced clinical practitioner for further assessment</p>
<p><b>Action to be taken if patient excluded</b></p>	<p>Patient should be referred to a more experienced clinical practitioner for further assessment</p>
<p><b>Action to be taken if patient declines treatment</b></p>	<ul style="list-style-type: none"> <li>• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment</li> <li>• This information must be documented in the patients’ health records</li> <li>• Any patient who declines care must have demonstrated capacity to do so</li> <li>• Where appropriate care should be escalated</li> <li>• Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options</li> </ul>

## 8. Details of the medicine

<p><b>Name, form and strength of medicine</b></p>	<p>Levonorgestrel 1500 micrograms (1.5mg) single dose (N.B. this is equivalent to 1.5mg levonorgestrel)</p>
<p><b>Legal category</b></p>	<ul style="list-style-type: none"> <li>• Pharmacy (P)</li> <li>• Prescription Only Medicine (POM)</li> </ul>

<p><b>Indicate any <u>off-label use</u></b> (if relevant)</p>	<p>Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the <u>Summary of Product Characteristics (SPC)</u></p> <p>This PGD includes off-label use in the following conditions:</p> <ul style="list-style-type: none"> <li>• Use between 72 and 96 hours post UPSI</li> <li>• Increased dose for individuals with BMI over 26kg/m<sup>2</sup> or weight over 70kg and in individuals using liver enzyme inducing agent</li> <li>• Severe hepatic impairment</li> <li>• Individuals with previous salpingitis or ectopic pregnancy</li> <li>• Lapp-lactase deficiency</li> <li>• Hereditary problems of galactose intolerance</li> <li>• Glucose-galactose malabsorption</li> </ul> <p>Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.</p> <p>Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.</p>
<p><b>Route/method of administration</b></p>	<p>Oral</p>
<p><b>Dose and frequency</b></p>	<ul style="list-style-type: none"> <li>• Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI</li> <li>• <b>Dose for those individuals taking enzyme inducing medicines or herbal products:</b> An individual who requests levonorgestrel whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI</li> <li>• <b>Dose for those individuals with a body mass index of more than 26kg/m<sup>2</sup> or who weigh more than 70kg:</b> An individual who requests levonorgestrel with a body mass index of more than 26kg/m<sup>2</sup> or who weighs more than 70kg can be offered a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI</li> </ul>

<b>Quantity to be administered and/or supplied</b>	<ul style="list-style-type: none"> <li>• Appropriately labelled pack of one tablet</li> <li>• Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m<sup>2</sup> or who weigh more than 70kg</li> </ul>
<b>Maximum or minimum treatment period</b>	<ul style="list-style-type: none"> <li>• A single dose is permitted under this PGD</li> <li>• If vomiting occurs within 3 hours of levonorgestrel being taken a repeat dose can be supplied under this PGD</li> <li>• Repeated doses can be given within the same cycle. Please note: <ul style="list-style-type: none"> <li>○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)</li> <li>○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)</li> </ul> </li> </ul>
<b>Storage</b>	Room temperature
<b>Adverse effects</b>	<p>The following side effects are common with levonorgestrel (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> <li>• Nausea and vomiting are the most common side effects</li> <li>• Headache, dizziness, fatigue, low abdominal pain and breast tenderness, diarrhoea</li> </ul> <p>The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time</p>
<b>Records to be kept</b>	The administration of any medication given under a PGD must be recorded within the patient's medical records

## 9. Patient information

<b>Verbal/Written information to be given to patient or carer</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• Verbal information must be given to patients and or carers for all medication being administered under a PGD</li> <li>• Where medication is being supplied under a PGD, written patient information leaflet must also be supplied</li> <li>• A patient information leaflet is available on request</li> </ul> <p>Verbal information must be given to patients and or carers for all medication being administered under a PGD. Where medication is being supplied under a PGD, written patient information leaflet must also be supplied. A patient information leaflet is available on request. When starting a hormonal method immediately after the administration of Levonorgestrel, see FSRH guidance on quick starting.</p> <ul style="list-style-type: none"> <li>• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception</li> </ul>
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<p><b>Verbal/Written information to be given to patient or carer</b> (continued)</p>	<ul style="list-style-type: none"> <li>• Ensure that a patient information leaflet (PIL) is provided within the original pack</li> <li>• If vomiting occurs within three hours of taking the dose, the individual should return for another dose</li> <li>• Explain that menstrual disturbances can occur after the use of emergency hormonal contraception</li> <li>• Provide advice on ongoing contraceptive methods, including how these can be accessed</li> <li>• Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur</li> <li>• Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective</li> <li>• Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern</li> <li>• Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs</li> </ul> <p>There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.</p>
<p><b>Follow-up advice to be given to patient or carer</b></p>	<ul style="list-style-type: none"> <li>• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately</li> <li>• The individual should be advised to seek medical advice in the event of an adverse reaction</li> <li>• The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned</li> <li>• Pregnancy test as required (see advice to individual above)</li> <li>• Individuals advised how to access on-going contraception and STI screening as required</li> </ul>



## 10. Appendix A

References
<ol style="list-style-type: none"><li>1. British National Formulary (BNF) available online: <a href="https://bnf.nice.org.uk">https://bnf.nice.org.uk</a></li><li>2. Nursing and Midwifery (2018) "The code" available online: <a href="https://www.nmc.org.uk">https://www.nmc.org.uk</a></li><li>3. Current Health Care Professions Council standards of practice</li><li>4. General Pharmaceutical Council standards</li><li>5. The General Optical Council</li><li>6. Electronic medicines compendium available online: <a href="https://www.medicines.org.uk">https://www.medicines.org.uk</a></li><li>7. NICE Medicines practice guideline "Patient Group Directions" <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>8. Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 Updated December 2018 <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/</a></li></ol>

## 11. Appendix B

Health professionals agreed to practice
<ul style="list-style-type: none"><li>• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor</li><li>• A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves</li></ul>

## 12. Appendix C

Records
<p>The consent of the individual and:</p> <ul style="list-style-type: none"><li>• If individual is under 13 years of age record action taken</li><li>• If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.</li><li>• If individual over 16 years of age and not competent, record action taken</li><li>• Name of individual, address, date of birth</li><li>• GP contact details where appropriate</li><li>• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight</li><li>• Any known drug allergies</li><li>• Name of registered health professional operating under the PGD</li><li>• Name of medication supplied</li><li>• Date of supply</li><li>• Dose supplied</li><li>• Quantity supplied</li><li>• Advice given, including advice given if excluded or declines treatment</li><li>• Details of any adverse drug reactions and actions taken</li><li>• Advice given about the medication including side effects, benefits, and when and what to</li></ul>

do if any concerns

- Any referral arrangements made
- Any supply outside the terms of the product marketing authorisation
- Recorded that supplied via Patient Group Direction (PGD)

Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.

All records should be clear, legible and contemporaneous.

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.