Patient Group Direction for the Supply of Levonorgestrel Emergency Hormonal contraception (EHC) as first line treatment from Accredited Community Pharmacies by an Accredited Warwickshire Pharmacist


After reviewing with an option to extend up to a further 12 months.

Clinical Department/Service: Community Pharmacy

Subject to all the conditions and criteria below, this Patient Group Direction allows a trained pharmacist in an accredited pharmacy to supply from the pharmacy, appropriately packaged, the named drug to patients for self-administration without the need for a prescription from a doctor. The pharmacist must have completed additional training and confirm that they are professionally competent to operate, and agree to work within, this Patient Group Direction. For further product information the Pharmacist should refer to the Summary of Product Characteristics and the BNF.

1. Clinical Condition

<table>
<thead>
<tr>
<th>1.1</th>
<th>Clearly define situation/condition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Emergency hormonal contraception is appropriate when the client presents within 72 hours of UnProtected Sexual Intercourse (UPSI - sex without contraception, condom split or leaked, missed pills)</td>
</tr>
<tr>
<td></td>
<td>• A relevant medical history should be taken from all clients in accordance with the protocol</td>
</tr>
<tr>
<td></td>
<td>• If more than 72 hours but less than 120 hours have elapsed, an alternative oral treatment or Intra-Uterine Contraceptive Device (IUCD) is still effective and should be discussed with the client. If agreeable, the client may be referred to a Family Planning Clinic or the client’s GP (if they provide this service), or any other GP accredited for urgent IUCD fitting service (This does not need to be the client's registered GP or practice).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.2</th>
<th>Criteria for inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Client with self-declared age of 13 years and over presenting in person and requesting EHC for her own use</td>
</tr>
<tr>
<td></td>
<td>• Note: under 16’s must be assessed using Fraser guidelines</td>
</tr>
<tr>
<td></td>
<td>• Presentation within 72 hours of UPSI</td>
</tr>
<tr>
<td></td>
<td>• Client taking interacting drugs (refer to BNF, drugs likely to reduce the efficacy of Levonelle-1500 include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin. [Issue two Levonelle 1500 tablets, advising client to take a single dose of two 1500 microgram tablets (unlicensed dose)]</td>
</tr>
<tr>
<td></td>
<td>• Previous supply of EHC in the same cycle - if client presents within 72 hours of most recent UPSI, consider EHC</td>
</tr>
</tbody>
</table>
1.3 Criteria for exclusion

- Presentation more than 72 hours after UPSI
- Previous untreated UPSI in same cycle within 5 days
- If the client has a history of any of the following then she must be referred to a doctor in accordance with the SLA.
  - Current breast cancer
  - Severe liver disease
  - Previous history of salpingitis or ectopic pregnancy
  - Abnormal vaginal bleeding
  - The last menstrual cycle was abnormal, late or absent [i.e. potentially already pregnant]
  - Inflammatory Bowel Disease or other similar disease, where diarrhoea and vomiting may affect absorption of Levonelle-1500
  - Previous severe clinical problems with hormonal contraception (excluding nausea)
  - Allergy or intolerance to levonorgestrel or any of the tablet ingredients/excipients (including lactose)
  - Client is currently taking ciclosporin
  - Acute porphyria

1.4 Cautions

As per BNF

1.5 Action if patient excluded

Explain reasons for exclusion with client and document.
- If presentation more than 72 hours after UPSI, refer urgently for consideration of IUCD (if this could be fitted within 5 days of the UPSI)
- If previous untreated UPSI in same cycle was within 5 days, refer as above.
- If more than 5 days, i.e. too late for IUCD, advise patient of risk of pregnancy, which will not be covered by EHC

If the client’s history excludes them from treatment, a copy of the Pharmacist Signpost letter (as per agreement) should be either sent to the client’s GP (if the client consents) or given to the client to take to her GP.

1.6 Action if patient declines or does not adhere to care under the protocol

Record any refusal of treatment
Emphasise the importance of treatment and potential risks if not treated e.g. Pregnancy

2. Description of Treatment

2.1 Name of medicine, strength, form, to be supplied

Levonorgestrel tablet 1500 micrograms (Levonelle 1500; Bayer)

2.2 Legal status

Prescription only medicine (POM)

2.3 Licensed or

Licensed
### 2.4 Dose(s)
One tablet should be taken as soon as possible, preferably within 12 hours, and no later than 72 hours after UPSI.

### 2.5 Route/Method of Administration
For oral administration (supervised administration is recommended).

### 2.6 Frequency of Administration
Single dose

### 2.7 Total dose and number of times treatment can be administered over what period of time
If the client is taking enzyme-inducing drugs, two Levonelle 1500 tablets should be issued, and the client advised to take both 1500 microgram tablets as a single dose. The client must be advised that this is an unlicensed dose.

### 2.8 Instruction on identifying and managing any possible adverse outcomes
If vomiting or severe diarrhoea occurs within three hours of taking the tablet, a second tablet may be given provided that it will be taken within 72 hours of the first UPSI of that cycle. Anti-emetics may be advised at the pharmacist’s discretion.

### 2.9 Procedure for reporting any suspected Adverse Drug Reactions (ADRs)
Use the yellow card at the rear of the BNF for reporting any adverse reactions.

### 2.10 Information on follow up treatment if needed
- Seek medical advice about any severe or persistent abdominal pain
- Advise to read and retain PIL in Levonelle 1500 pack
- Emphasise that Levonelle 1500 is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure.
- If a client experiences any of these:
  - No period within 28 days of taking EHC
  - Period delayed by more than 5 days
  - Period that is unusual or exceptionally light
- Advise client to visit her GP or a Family Planning Clinic with a sample of early morning urine for a pregnancy test.

### 2.11 Detail arrangements for referral to medical advice
Advise client to consider long-term methods of contraception and consult their GP or family planning clinic for advice on future methods of contraception.

### 2.12 Written/verbal advice for patient/carer before/after treatment. Product information leaflet should be given to the patient
Each client must be given the client information leaflet (as per Service Specification) before leaving the pharmacy. The pack must always be labelled with the following information:
- Date of issue, pharmacy name & address and ‘Keep out of the reach of children’ and packaged in an opaque bag.
- A supply of three condoms should be offered wherever possible and appropriate patient information given as below.
  - Mode of action - Thought to be primarily due to inhibition of implantation.
  - Failure rate - Between 1 and 5 women out of 100 women will become pregnant despite EHC i.e. up to one in twenty.
  - Foetal effects - There is no evidence that EHC causes abnormalities if a pregnancy does follow.
  - Risk of ectopic pregnancy – Cases have occurred, and the
possibility should be mentioned, particularly to clients with a known previous ectopic pregnancy
- STI risk – offer Chlamydia screen (under separate service) and signpost for GUM assessment if client is appropriate
- Future contraception – discuss future contraception needs and signpost to contraceptive provider

**Side Effects** Consult current BNF for full list.
- Common side effects include bleeding not related to period, headache, nausea, low abdominal pain, fatigue
- Common side effects include breast tenderness, delay of menses more than 7 days, irregular bleeding, dizziness, diarrhoea and vomiting

### 2.13 Method of recording supply / administration

The following should be recorded either in the computer patient medication record or paper record (i.e. EHC Appendix 1):
- Assessment of client need in relation to the intervention
- If client under 16 document competence under Fraser guidelines (1985) as per local protocol
- Date of supply/administration
- Name of medication supplied
- Batch number and expiry date
- Advice given and leaflet supplied
- Contraceptive (i.e. condoms) offered/supplied

### 3. Characteristics of staff

#### 3.1 Details of qualifications and registration of individual professional operating under this PGD

Pharmacist registered with The General Pharmaceutical Council (GPhC)

#### 3.2 Specialist qualification, training, experience and competence necessary and relevant to the clinical condition to be treated and medicines used in this protocol

Has completed CPPE learning programmes to provide necessary knowledge to underpin the provision of this service:
1. Emergency contraception *(CPPE 2012; e-learning)*
2. Contraception *(CPPE 2009; Open Learning)*
3. Safeguarding children and vulnerable adults *(CPPE 2012; e-learning)*

Where the learning programme provides pharmacists with an assessment or record of completion this must be kept by the pharmacist and a copy sent to the accrediting PCT.

Has confirmed competence and confidence around administration of Levonorgestrel EHC under PGD

#### 3.3 Continued training requirements

It is the responsibility of the practitioner to maintain own level of competency
The practitioner should be aware of any change to the recommendations for the medicine listed
4. Management and monitoring of Patient Group Direction:

PGD developed by:

<table>
<thead>
<tr>
<th>Name &amp; Designation</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor Dr J Linnane</td>
<td></td>
<td>28 Feb 2013</td>
</tr>
<tr>
<td>Director of Public Health NHS Warwickshire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist Dave Maxted</td>
<td></td>
<td>28 Feb 2013</td>
</tr>
<tr>
<td>Senior Pharmaceutical Advisor NHS Warwickshire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community Pharmacist Faye Chapman</td>
<td></td>
<td>28 Feb 2013</td>
</tr>
<tr>
<td>Chair Warwickshire Local Pharmaceutical Committee</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Declaration by authorising body:

This PGD has been authorised by John Linnane Director of Public Health on behalf of NHS Warwickshire

Signature:  
Date: 28 Feb 2013
5. **Standing Order for Levonorgestrel EHC PGD**

**Part One - Agreement by Pharmacist**

- I consider I am competent to supply Levonorgestrel EHC under this PGD.
- I have completed the necessary Centre for Pharmacy Postgraduate Education (CPPE) Learning:
  - Emergency contraception (CPPE 2012; e-learning)
  - Contraception (CPPE 2009; Open Learning)
  - Safeguarding children and vulnerable adults (CPPE 2012; e-learning)
- I have submitted a copy of my CPPE certificates to the PCT
- I have read and understood the Patient Group Direction and agree to use it in accordance with the criteria described.

Pharmacist Name: ________________________________

Pharmacist GPhC number: ________________________________

Signature: ________________________________

Business Address: ________________________________

Date: ________________________________

**Part Two (to be completed by the Commissioner)**

- The above named pharmacist is identified as being suitably qualified in the supply of Levonorgestrel EHC
- This pharmacist has confirmed competency in the supply of Levonorgestrel EHC according to this Patient Group Direction
- The above named pharmacist is hereby authorised to operate this PGD within any **accredited** Warwickshire community pharmacy

Authorised by:

Name: ________________________________

Position: ________________________________

Signature: ________________________________

Date: ________________________________

**Guidance notes**

- Each pharmacist should complete and sign part one of the Standing Order
- Part two will be completed by an authorised person at NHS Warwickshire
- When both parts one and two are completed and signed:
  - The original will be kept by the Commissioner
  - A copy will be returned to the pharmacist
- A copy of the completed standing order should be kept in each pharmacy where a pharmacist provides the service, and retained by the accredited pharmacist

Return this completed signed agreement to: Ann Gill, Business Support /Office Manager
Public Health Warwickshire, PO Box 43, Shire Hall Warwick CV34 4SX Tel: 01926 413775
Fax: 01926 410130 Anngill@warwickshire.gov.uk
6. Clients under the age of sixteen, and aged 13 yrs & over - The Fraser Guidelines

The Fraser Guidelines (1986) set out good practice for health professionals for the treatment of the under 16 age group without parental consent. This is considered appropriate if the following criteria are met (see below)

In considering the provision of advice or treatment on contraception, doctors and other professional staff need to take special care not to undermine the parental responsibility and family stability. The doctor or other health professional should, therefore, always seek to persuade the young person to tell their parents or guardian (or other person in loco parentis) or let the doctor inform them, that contraceptive advice is being sought and the nature of any advice or treatment that is given.

Exceptionally, there will be cases where it is not possible to persuade the young person either to inform the parents or to allow the doctor or other health professional to do so. This may be, for example, where family relationships have broken down. In such cases, a doctor or other health professional would be justified in giving advice and treatment without parental knowledge or consent, provided the doctor or other health professional was satisfied that:

Fraser criteria:

1. The young person could understand the advice and had sufficient maturity to understand what was involved in terms of the moral, social and emotional implications.
2. That the young person could not be persuaded to involve the parents, nor would they allow notification to the parent that contraceptive advice was being sought.
3. That the young person would be very likely to begin or continue having sexual intercourse with or without contraceptive treatment.
4. That without contraceptive advice and treatment, the young person's physical and/or emotional health would be likely to suffer.
5. That the young person's best interests required the doctor or other health professional to give contraceptive advice and/or treatment, without parental consent.

If a client is believed to be under 16 years of age (and at least 13 years or over), the pharmacist will assess the client’s competence as per the Fraser Guidelines, and a separate section to the proforma (see SLA) will be completed. 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.

1. Understanding of advice given.
2. Encouraged to involve parents
3. The effect on the physical or mental health of young person if advice / treatment withheld
4. Action in the best interest of the young person

NHS Warwickshire advises the use of the Warwickshire Social Care Support for Children and Families team where there is more information on sexual activity of young people under the age of 18
http://www.warwickshire.gov.uk/supportforchildrenandfamilies
7. Guidelines for missed pills & use of Emergency Hormonal Contraception (EHC)

There is no time in the menstrual cycle when there is no risk of pregnancy, particularly if the woman reports having irregular periods or is unsure of her dates, although the risk in the first 3 days is negligible.

Recommendations* for emergency contraception use in commonly occurring situations:

<table>
<thead>
<tr>
<th>Situation</th>
<th>Indications for emergency contraception</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unprotected sex</strong></td>
<td>• Consensual sex, no contraceptive methods used</td>
</tr>
<tr>
<td></td>
<td>• Rape or sexual assault with risk of pregnancy</td>
</tr>
<tr>
<td></td>
<td>• Coitus interruptus / failed coitus interrupt</td>
</tr>
<tr>
<td></td>
<td>• Ejaculation on external genitalia</td>
</tr>
</tbody>
</table>

**Potential failures of various contraceptive methods**

- **Combined pills**: If *three or more* 30-35 microgram EE or *two or more* 20 microgram EE pills have been missed in the first week of pill taking (ie days 1-7) and UPSI occurred in week 1 or the pill-free week.
- **Progestogen-only pills**: If *one or more* POPs have been missed or taken >3 hours late (>12 hours late for Cerazette®) *and* UPSI has occurred in the 2 days following this.
- **Intrauterine contraception**: If complete or partial expulsion is identified or mid-cycle removal of an IUD/IUS is deemed necessary *and* UPSI has occurred in the last 7 days.
- **Progestogen-only injectables**: If the contraceptive injection is late (>14 weeks from the previous injection for medroxyprogesterone acetate or >10 weeks for norethisterone enantate) *and* UPSI has occurred.
- **Barrier methods**: If there has been failure of a barrier method.

**Use of liver-enzyme inducers**

- **Liver enzyme-inducing drugs (including St John’s Wort)**: An additional barrier method is recommended if oral contraceptives, progestogen implants or contraceptive patch and liver enzyme-inducers are taken concurrently. EHC is indicated if there is UPSI or barrier method failure during, or in the 28 days following, use of liver enzyme-inducers.

* Faculty of Family Planning & Reproductive Healthcare Clinical Effectiveness Unit (April 2006)