

**General Policy for the Provision of
Emergency Hormonal Contraception Service
under a Patient Group Direction (PGD)
by Community Pharmacists in Community Pharmacy Premises
with in Peterborough Primary Care Trust**



To be read in conjunction with the Chlamydia Screening Site Guide, C-Card Guidelines, Levonelle PGD.

1. Aim and Objectives

Aim

To reduce the number of unintended conceptions within the Peterborough Primary Care Trust (PPCT) area through multi-professional partnership working and by extending emergency contraception provision.

The client group for which the service is intended is women under the age of 24 years who present at a participating community pharmacy requesting access to emergency contraception services.

Objectives

To improve access to emergency hormonal contraception (EHC) as Levonelle 1500® via appropriately trained community pharmacists working to an agreed Patient Group Direction (PGD).

To provide immediate advice on contraception and to direct the client to long term contraceptive services.

To provide a non-judgemental, supportive environment where women feel able to discuss their concerns and ask questions.

To provide condoms using the C-Card scheme where appropriate.

To raise awareness and give assurances of the confidentiality of other locally provided services (family planning, specialist sexual health services).

To provide access to Chlamydia Screening services (postal kits) where appropriate.

To build partnerships and increase communication between community pharmacists and other agencies responsible for sexual health provision to young people.

To monitor and evaluate the outcomes of the service.

2. Eligibility to supply Levonelle 1500® under the Patient Group Direction

Levonelle 1500® may **only** be supplied by a pharmacist who has received the appropriate training as described in Section 3 (Training) below, (subsequently referred to as an *accredited* pharmacist), and has agreed to act in accordance with the PGD for Levonelle 1500® and General Policy Requirements of the service

In addition, the supply may **only** be made from a Community Pharmacy with an appropriate current PCT Service Level Agreement in place

(subsequently referred to as "*the provider*")

The pharmacist who will undertake the role must have the full support of his/her Superintendent Pharmacist where appropriate.

Pharmacists who provide locum community pharmacy services must ensure that their accreditation is recorded by **each** PCT in whose pharmacies they work and by **each provider** pharmacy in which they offer the service.

3. Training

In order that a pharmacist be approved by the PCT and therefore act as an *accredited* pharmacist for providing this service, they **must**:

- have attended appropriate training as deemed necessary by the PCT

- provide evidence of completion of the Centre for Pharmacy Postgraduate Education (CPPE) workshop or open learning module on emergency hormonal contraception

- maintain clinical knowledge appropriate to their practice and make themselves aware of appropriate current literature

The *accredited* pharmacist will be expected to

- train pharmacy staff on responding to requests for emergency contraception when the accredited pharmacist is present and on the procedure to be followed to assist the client to access an alternative service when an accredited pharmacist is unavailable

- participate in surveys of activity relating to the service.

4. Premises

The service may only be provided from a Community Pharmacy with an appropriate current PCT Service Level Agreement in place.

The provider must agree to provide a consultation room for confidential consultation with clients

The provider should display a notice that an Emergency Contraception Service is offered, preferably indicating when an accredited pharmacist is available to provide the service.

An accredited pharmacist will normally be available within the pharmacy for a minimum of 30 hours per week. If no accredited pharmacist is available when a client presents to the pharmacy, then the client must be given positive assistance by the available staff to access an appropriate alternative service.

5. Indemnity

The pharmacist must confirm that they have current professional indemnity insurance that specifically includes the supply of Emergency Hormonal Contraception under a Patient Group Directive

6. Patient Confidentiality

Pharmacists should familiarise themselves with the guidance provided by the Royal Pharmaceutical Society, Code of Ethics and Standards, Part 2, Standards of professional performance, Section C, Confidentiality.

*“The public expects pharmacists **and their staff** to respect and protect confidentiality. This duty extends to any information relating to an individual, which pharmacists or their staff acquire in the course of their professional activities. Confidential information includes personal details and medication, both prescribed and non-prescribed.”*

The pharmacist must ensure that any information of a confidential nature acquired in the course of carrying out their duties, under this policy, is disclosed only with the consent of the individual other than in circumstances defined in points (b) (i) to (vi) and that they comply with points (c) to (g) as stated in the Code of Ethics and Standards.

Pharmacists **and their staff** must regard all personal and clinical information relating to clients as confidential and should be particularly aware that information about services provided to adolescents should not normally be disclosed to their parents without the consent of the young person.

Pharmacists should also take care to protect confidentiality of information relating to other patients and clients that may be visible in areas used for confidential interview.

7. Intended Outcomes

The pharmacist is able to decide whether a supply of Levonelle 1500® is appropriate for the client making the request for emergency hormonal contraception

The client is able to make an informed choice about whether to use Levonelle 1500® or other methods of emergency contraception.

Where a supply of Levonelle 1500® is made, the client is given information about the treatment and when to seek further help and advice.

Where a supply of Levonelle 1500® is not provided, the client is recommended to consult with a GP or Family Planning service for further advice.

Each client is provided with immediate advice on contraception and made aware of the necessity to use a regular and reliable method of contraception for the longer term.

The availability of such methods, along with support and follow up, through Family Planning and GP services is emphasised.

8. Client Groups

The client group, for which the service is intended, is women under the age of 24 years who may require emergency contraception and who present at a community pharmacy provider. Clients may self-refer or may be referred by other Healthcare Professionals, including other pharmacists.

If a client is known or believed to be less than 16 years, the pharmacist **must** assess the client's competence (Fraser ruling) and complete the appropriate section of the Client Record Sheet.

In **very exceptional circumstances** women 24 years and over may be supplied Levonelle 1500® under the terms of the PGD if they would otherwise be unable to obtain a supply from another NHS source within the 72-hour limit.

Pharmacists making a supply in such circumstances must indicate the reason for the supply on their claim for payment. The frequency of supplies made in such circumstances will be closely monitored.

9. Clients Under 16 Years

The Fraser ruling in 1985 established the current legal position in England and Wales, which states that people under the age of sixteen are legally able to consent on their own behalf to medical, or dental procedures or treatment.

In considering the provision of advice or treatment on contraception, doctors and other professional staff need to take special care not to undermine parental responsibility and family stability. The doctor or health professional should therefore, always seek to persuade the young person to tell their parents or guardian (or other person in *loco parentis*) or to 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 health professional to do so. In such cases, a doctor or other health professional would be justified in giving advice and treatment without parental knowledge or consent provided that the doctor or other health professional was satisfied that the Fraser Guidelines were met:

The Fraser Guidelines

1. The young person can understand the advice and has sufficient maturity to understand what is involved in terms of moral, social and emotional implications.
2. The young person cannot be persuaded to involve the parents, nor will they allow notification to the parent that contraceptive advice was being sought.
3. The young person will be very likely to begin or continue to have sexual intercourse with or without contraceptive treatment.
4. Without contraceptive advice or treatment the young person's physical and/or emotional health will be likely to suffer
5. The young person's best interests require the health professional to give contraceptive advice and/or treatment without parental consent

Source: *The Fraser Ruling: Gillick v West Norfolk and Wisbech Area Health Authority (1985)*

The Fraser guidelines in practice

If a client is believed to be under the age of sixteen, the pharmacist should:

1. Assess the maturity of the client in terms of understanding any advice given
2. Encourage the client to involve her parents
3. Consider the effect on the physical or mental health of the client if advice or treatment is withheld
4. Make a decision as to whether the client's best interests require the provision of contraceptive advice or supplies or both without parental consent

Where the pharmacist does not consider a young person "competent", a supply of Levonelle 1500® may not be provided. The pharmacist should recommend (and assist where necessary) the client to attend their GP or a Contraception and Sexual Health Clinic (CaSH) from whom they may receive advice, support and be provided with EHC if appropriate.

Regardless of whether a supply of Levonelle 1500® is made, the confidentiality of the consultation must be respected, unless there are convincing reasons to the contrary.

Child Protection Issues

When seeing a person under the age of 16 years, pharmacists may have concerns that the young person is the victim of sexual abuse, or being exploited in prostitution. If such concerns arise, the Peterborough Area Child Protection Procedure must be followed.

The young person should be advised "that information given is confidential, unless on reflection I consider that you or other young persons may be at risk of suffering significant harm through abuse or exploitation. I have a duty to share my concerns with the Access Team at your local Social Services Department and I request your agreement to do this. However, my concerns are such that should you refuse, I will inform them of my concerns".

10 Support Network

The accredited pharmacist must feel confident to refer to other sources of information and support including other participating pharmacists, the Family Planning Service, NHS Direct, Family Planning Nurses, and GP's subject to the requirement for confidentiality.

11. Medical Referral

The client must always be advised to talk to her GP or Contraception and Sexual Health Clinic, regardless of whether a supply is made. Where the circumstances are outside the PGD, or where there are medical concerns, or the client wishes it, the client should be referred to a GP or specialist Contraception and Sexual Health Clinic. Guidance and information are to be offered to all clients about accessing either GP contraceptive services or Contraception and Sexual Health Clinic for ongoing contraception.

12. Managing the Consultation in the Pharmacy

All requests for emergency contraception must be dealt with sensitively and discreetly. Pharmacy staff must refer all such requests to the accredited pharmacist. Clients must be seen as soon as possible. If this cannot be immediate, then the client must be given a time to return or they must be directed to the nearest alternative pharmacy or to another suitable provider.

Requests by third parties

The pharmacist must personally interview and counsel the client requesting emergency contraception and Levonelle 1500® may only be supplied, in person, to the intended user. Pharmacists may respond to requests for advice by telephone and by third parties by providing appropriate information for the intended user.

Information to be obtained during the consultation

Before making any recommendation regarding supply of Levonelle 1500® the client should be questioned to ensure that supply would be appropriate and in accordance with the Patient Group Direction

The Client Record Sheet should be completed by the pharmacist and signed by the client. Refusal by the client to disclose information required for audit purposes (postcode and ethnicity) or to sign the record sheet should be noted by the pharmacist but are not considered grounds to withhold an appropriate supply.

Supply of Levonelle 1500®

*The [P] product of Levonelle must **not** be used, as the licensing and patient information leaflets are different.*

A single pack of one tablet (equivalent to 1500 micrograms levonorgestrel) can be supplied if:

The pharmacist is satisfied that supply is appropriate within the terms of the PGD.

The client has been counselled according to the requirements of the PGD and that the client understands the advice that has been given.

The product is supplied for immediate use and not for possible future use.

The pack must be labelled with the following information:

The name of the client

The pharmacy address

The date of supply

The warning 'Keep out of the reach of children'

The Patient Information Leaflet (PIL) should be enclosed

Directions

1500mcg levonorgestrol should be taken as a single dose, as soon as possible, preferably within 12 hours, and no later than 72 hours after unprotected intercourse.

Advice

The pharmacist must ensure that the client has received the manufacturers Patient Information Leaflet for Levonelle 1500® and appropriate additional information leaflets.

Vomiting is possible but unlikely. If vomiting occurs within three hours of taking the tablets, another tablet can be supplied and should be taken as soon as possible and the client must seek further advice immediately from the pharmacist, GP or Contraception and Sexual Health Clinic for consideration of a repeat dose and/or consideration of other options, such as the IUD.

The client should visit a Contraception and Sexual Health Clinic or GP if they experience abdominal pain, faintness, or if their next period is different from normal or does not occur within three weeks of the dose of Levonelle 1500®.

There is a risk of failure with EHC and it is not a suitable contraceptive method for repeated use.

The effectiveness of regular methods of contraception must be stressed and information about the options for long-term contraception provided.

After using emergency contraception a barrier method (e.g. condom) should be used until the next menstrual period starts.

The use of Levonelle 1500® does not contraindicate the continuation of regular hormonal contraception. If the need for emergency contraception is because of missed pills then the client should be informed to continue normal pill taking and to use additional contraceptive protection for seven days.

13. Payment and Record Keeping

The consultation fee for each client is £13.00

Reimbursement for the price of the Levonelle 1500® tablet will be £6.00(including VAT)* per pack.

(* see current Chemist & Druggist Price List)

The pharmacy is responsible for financing operational aspects of the specified service from within the agreed fee. This will include all telephone costs, postage costs, stationery costs and other miscellaneous costs associated with delivery of the service

The accredited pharmacist must complete all necessary paperwork and collect agreed data to enable monitoring and evaluation of the Scheme. Claims may be submitted for any reasonable combination of the four elements of the scheme as dictated by the individual circumstances. NB A consultation fee should not be claimed if a client is purely receiving a C-Card administration (supply), but may be claimed if registering a new patient or in conjunction with another element of the scheme.

Payment to the pharmacy will be by Peterborough PCT on a monthly basis. Claims should be received by the 5th of each month, for the preceding period, and forms must be completed clearly and in full to enable prompt payment to occur.

Peterborough PCT shall notify the Pharmacy as soon as practicable if it considers that a claim submitted is incomplete or incorrect or that the stated service has not been provided in accordance with this policy. In such circumstances payment may be withheld until the issue has been resolved.

Client Record Sheet

A record of the consultation and its outcome must be made for each client using the Client Record Sheet provided.

Where available, a note of supply should also be made in the client's patient medication record.

The Client Record Sheet represents a medical record of the consultation and must be kept for 10 years after the last attendance or up to the patient's 26th birthday if longer than 10 years away. All completed records must be stored in a secure place.

Activity monitoring and claim form

Selected information taken from the Client Record Sheet is required for the purposes of evaluation and audit of the Scheme and to enable payment to be made to the pharmacy.

14. Adverse Drug Reactions (ADRs)

Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. Pharmacists operating within this Scheme are asked to report all serious suspected adverse reactions to Levonelle 1500®, even if the effect is well recognised (See BNF for supporting information).

ADRs should be reported to Medicines and Healthcare products Regulatory Agency(MHRA), using the yellow card system. Cards are available in the BNF. A client presenting with a suspected ADR should be referred to a doctor for further investigation.

15. Risk Management

Complaints

All complaints received by the pharmacy in relation to this service should be dealt with in accordance to the pharmacy-based system for handling complaints.

Although pharmacists will be expected to undertake their own investigation and management of any incident/complaint, copies of documentation relating to any such incident must be copied to the PCT Clinical Governance Manager.

Serious Adverse Events

A Serious Adverse Events (SAE) is defined as any incident which may

seriously impact upon the delivery of service and/or
reflect a serious breach of standards or quality of service and/or
result in litigation and/or
attract media attention

Where a SAE has occurred, a completed report should be forwarded to the Clinical Governance Lead at the PCT. For further advice contact the PCT Clinical Governance Team. Information received by the PCT will be treated in strict confidence.

Dealing with Media Enquiries

Experience within similar Schemes elsewhere is that media attention about aspects of the service is particularly likely to occur. For further advice contact the PCT Communications Team.

References

- Summary of Product Characteristics for Levonelle 1500® (Current issue)
- Faculty of Family Planning and Reproductive Health Care (Royal College of Obstetricians and Gynaecologists), 'Emergency Contraception: Recommendations for clinical practice' –British Journal of Family Planning June 2003, **29** (2): 9-16
- British National Formulary – Current edition
- Medicines, Ethics and Practice – A guide for pharmacists. Current edition
- Ellison J et al. Apparent interaction between warfarin and levonorgestrel used for emergency contraception. Br Med J 2000; 321: 1382
- Health Service Circular HSC 2000/026. Patient Group Directions (England Only)
- Health Service Circular HSC 1998/217. Preservation, Retention and Destruction of GP General Medical Services Records Relating to Patients.
- Complaints: Guidance for Community Pharmacists PSNC website.

This policy will be reviewed where any change to evidence-based knowledge about this product or any new relevant published guidelines from the MHRA or Faculty of Family Planning and Reproductive Health Care becomes available.