



Working in partnership

Locally Commissioned Service

Service Agreement

Emergency Hormonal Contraception

Camden and Islington

1st April 2019 – 31st March 2020

The 2019/20 service specification is a continuation of the 2018/19 specification with the following changes:

- Clarification around eligibility (Section 1.1)
- Clients should be instructed to self-report their height and weight as part of the service (Section 1.8)
- Flowchart to support providing the drug (levonorgestrel or ulipristal) as part of the service (Section 7, and refer to levonorgestrel and ulipristal PGDs)

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Emergency Hormonal Contraception Locally Commissioned Service

Service specification

1.0 Service specification

1.1 Overview

The service can be provided to Female clients aged 13 to 24 (inclusive) requesting Emergency Hormonal Contraception (EHC) following an incident of Unprotected Sexual Intercourse (UPI) or failure of a contraceptive method, with the aim of preventing unplanned pregnancy. This service must be provided in line with the criteria specified by the Patient Group Direction for the provision of EHC.

1.1.1 This service is currently available to residents from out of borough, who are residents of the United Kingdom. Non United Kingdom residents should be signposted to a GP surgery to register as a temporary resident, or purchase EHC from a pharmacist.

1.1.2 The Pharmacy owner and accredited pharmacist(s) will participate in any new developments in either practice or service, instigated by Camden and Islington Public Health.

1.2 Eligibility to provide service and training

1.2.1 This service can only be provided by accredited pharmacists who have satisfactorily completed all training required by Camden and Islington Public Health Department. Provision must be in line with the current London Patient Groups Direction for the provision of EHC

1.2.2 The pharmacy must be satisfactorily complying with its obligation under Schedule 1 to the Pharmaceutical Services Regulations to provide essential services and must meet all the governance requirements in the current Community Pharmacy Contractual Framework.

1.2.3 The Pharmacy owner must ensure that all pharmacy staff members who have contact with potential clients are trained accordingly. This will include areas such as confidentiality, knowledge of alternative services in the area and how to seek urgent advice.

1.3 Service availability

1.3.1 Any requesting client will be seen as soon as possible. If they are unable to be seen immediately they must be given a time at which to return. This time must be within the next 30 minutes.

1.3.2 It is the responsibility of the pharmacy owner to have a full and current list of all accredited pharmacy and sexual and reproductive health services in the area, in order to signpost all potential clients if they are unable to provide the service within the timeframes specified in 1.3.1. This information can be found on NHS Choices and Ur Life (Camden pharmacies only). Commissioners will also be able to provide these contact details.

1.3.3 The Pharmacy owner must provide Camden and Islington Public Health with information on service availability and must advise on any changes to this availability.

1.3 Premises

1.4.1 The pharmacy must comply with the standards checklist for registered pharmacy premises. The pharmacy premises must have a designated consultation area in which the client can be seen and privacy can be maintained. Should the issue of chaperoning need to be addressed, the pharmacist may offer a quiet area within the pharmacy where privacy is still maintained. The client must at all times feel comfortable and confident in her surroundings.

1.5 Data collection and storage

1.5.1 Every client contact must be recorded on the Webstar consultation form.

1.5.2 The online consultation forms are to be treated as confidential. Access to the records is for approved staff only. All records must comply with General Data Protection Regulations.

1.6 Confidentiality

1.6.1 Client confidence in confidentiality is paramount. Pharmacy owners, pharmacists and pharmacy staff must all understand and respect the issue of confidentiality. No information may be given to a third party without prior consent of the Client. This issue of confidentiality applies equally to clients under the age of 16 years.

1.6.2 Pharmacists may need to share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements, including, where appropriate, the need for the permission of the client to share the information.

1.6.3 Clients must be shown a copy of the confidentiality statement (included at the end of the specification) at the start of the consultation. When holding a consultation with a client under 18 years of age, pharmacists should clearly explain confidentiality to the young person, explaining that “the information you give is confidential unless I consider that you or some other young person is at risk of suffering emotional or physical harm. In these exceptional circumstances I have a duty to share this information with other health professionals such as ‘the children and family team at social services’. Hopefully, this can be done with your agreement, but this is not always required.”

1.7 Health promotion

1.7.1 As well as supplying EHC, the Pharmacist also has a duty to provide the client with appropriate contraceptive information and advice, in both verbal and written forms, and associated health promotion advice/literature. Pharmacists should signpost clients to other primary and secondary care providers as well as provide information on the use of regular contraceptive methods (including advice on the use of condoms and information on long-acting reversible contraception and where to access these services).

1.7.2 In addition, every client contact should be given verbal and written advice on the avoidance of sexually transmitted infections and signposted to appropriate services.

1.7.3 The pharmacist should stress that this supply of EHC takes care of this episode of unprotected sex only and make sure the client understands that they are not protected against pregnancy from any future incident of unprotected sexual intercourse.

1.7.4 The pharmacist will encourage the client to do a chlamydia screen and signpost where appropriate.

1.7.5 Each client should be given an information pack containing details of local sexual health clinics and 3 condoms. It is the responsibility of the pharmacy to order these packs in line with local procedures. Information on how to obtain these is available from commissioners.

1.8 Providing the drug

1.8.1 Pharmacists will supply emergency hormonal contraception (EHC) when appropriate to clients in line with the requirements of the latest Patient Group Direction (PGD).

1.8.2 The pharmacist must personally speak with and counsel the person requesting EHC. Advice may be given over the telephone, but EHC can only be supplied, in person, to the intended user. If a person requests a supply on behalf of another, the pharmacist must ensure that they are given appropriate advice and information to pass on to the intended user but cannot issue a supply of EHC.

1.8.3 Clients should be informed that it is possible that higher weight or BMI could reduce the effectiveness of Levonorgestrel. Clients should be instructed to self-report their height and weight to ensure they are given the recommended emergency contraception as per the guidelines in the PGD.

1.8.4 A verbal warning should be given that the tablet may be associated with nausea or vomiting. Pharmacist should explain to the client that, if vomiting or severe diarrhoea occurs within 2 hours of taking the tablet, the client should seek further advice from a pharmacist, GP or sexual health service.

1.9 Duty of care and follow up:

1.9.1 The pharmacy owners and accredited pharmacists have a duty of care towards their client group. If a client uses the service repeatedly it is the duty of the pharmacist to try and counsel the client and direct them to an appropriate provider, such as their general practitioner or a sexual and reproductive health service.

1.9.2 Clients excluded from the PGD criteria will be referred to another local service that will be able to assist them, as soon as possible, e.g. sexual health service, GP or will be invited to purchase the pharmacy medicine product if the exclusion from supply via the PGD is only due to an administrative matter, e.g. clients aged 25 years and over.

1.9.3 Clients who have exceeded the time limit for ellaOne® will be informed about the possibility of use of an IUD and should be referred to a local service or GP as soon as possible.

1.10 Advertising and promotion of service

1.10.1 The pharmacy owner must designate specific window space or a suitable alternative, to advertise the availability of this service and how else to obtain this service locally.

1.11 Monitoring and Payment

Remuneration for any pharmacy services and/or reimbursement for medication supplied in relation to this enhanced service will be withheld if this SLA is not signed by both the contractor and the commissioner. A copy must be held by the contractor and the commissioner as evidence of a signed agreement between both parties.

1.11.1 The Public Health Department will monitor the performance of each individual pharmacy on a monthly basis. The Pharmacy owners must ensure that all consultations are entered onto the Webstar system no later than the 5th day of each month for Islington pharmacies. Camden pharmacies can submit until the 10th day of each month.

1.11.2 If a woman is eligible under the criteria specified in this SLA and the accompanying PGD, then the supply will be made free of charge to the client at the commissioner's expense.

1.11.3 Service providers will receive a fee per consultation of £18.00. The fee per consultation will be paid irrespective of whether Levonelle1500® or ellaOne is supplied as long as the client is eligible for the service and the consultation follows the SLA and the PGD guidelines.

1.11.4 Reimbursement for drug supply will be for the NHS Drug Tarrif price of Levonelle 1500® and ellaOne, plus VAT. **Please note:** Levonelle One Step ® is not covered by this LCS and should not be supplied as it will not be reimbursed.

1.11.5 In Camden, use of the e-invoicing system is a requirement for delivering the EHC service. At the start of each month, the pharmacy must submit their invoice for the previous month's activity online using the e-invoicing system.

2.0 Age of consent and The Fraser Ruling.

The legal age of consent for medical treatment is 16 years or over, as determined by Section 8 of the Family Law Reform Act, 1969 (However, it should be noted that a 'child' is defined by the Children Act 1989 as anyone who has yet to reach their 18th birthday). In such cases, there is no legal requirement to obtain consent from a parent or guardian. The question of the rights of children under 16 years of age to consent to treatment on their own behalf was reviewed by the House of Lords, in connection with contraception (Gillick v West Norfolk and Wisbech Area Health Authority [1985]). The House of Lords ruled that young people under the age of 16 years could give valid consent to medical treatment, as long as they had sufficient understanding and intelligence to appreciate fully what is proposed, and are capable of expressing their own wishes (now referred to as the Fraser ruling).

This ruling stated that health professionals should consider the following issues before giving contraceptive advice/treatment when seeing young people under 16 years of age:

- Whether the young person understands the potential risks and benefits of the treatment and any advice given.
- The value of parental support should be discussed, and health professionals must encourage the young person to discuss their consultation with their parents. **Although the health professional is legally obliged to discuss the value of parental support, he/she must respect confidentiality.**

- The health professional should take into account whether the young person is likely to begin or continue having sexual intercourse with or without contraception or treatment.
- The health professional should assess whether the young person's physical and/or mental health will suffer if they do not receive contraceptive advice or supplies or treatment.
- The health professional should consider whether it is in the young person's best interest to receive contraceptive advice and/or treatment without parental consent.
- The healthcare professional should consider the possibility of sexual abuse and sexual exploitation in all cases.

If the pharmacist has any concerns relating to a possible need to breach confidentiality for the above reasons, please contact clinical support or social services in the presence of the young person. Do not act in isolation.

When a young person is judged not to be competent in line with the Fraser ruling, she should be referred to the young people's sexual health services or their GP. If the non-competent young person attends with a parent and both agree to treatment, then Levonelle 1500® or ellaOne can be given and both sign the PGD record sheet.

If the non-competent young person attends with a parent but the young person does not agree to treatment they must be referred to a sexual health service or GP.

3.0 Confidentiality and Child Protection.

A number of issues have arisen concerning the provision of emergency hormonal contraception (EHC) to young people following the Laming report and changes in the law (Sexual Offences Act 2003). These have given rise to a revision of *Best Practice Guidance For Doctors And Other Health Professionals On The Provision Of Advice And Treatment To Young People Under 16 On Contraception, Sexual And Reproductive Health*.

Below is an outline of your duties regarding provision of EHC to young clients and your obligations regarding confidentiality following these changes.

Sexually active young people under the age of 13

You are not covered by the EHC patient group direction (PGD) to provide EHC to clients under the age of 13 under any circumstances through this scheme. However, you are under a positive duty to secure treatment for the client from a local GP or sexual health clinic. You must keep a record with details of the client and actions you have taken and you must immediately inform the relevant Child Protection Team or Social Services (see below).

The law is very strict with respect to children under 13. A child under the age of 13 does not, under any circumstances, have the legal capacity to consent to any form of sexual activity and there is no legal defense for any person who has a sexual relationship with someone under 13 years. It is important to be aware that in all cases where the sexually active young person is under the age of 13, there must be a discussion with the local social service and/or police team. Further advice can also be sought from the Child Protection Advice and Support Teams (see Section 4.0). Confidentiality must be waived in the interest of the young person.

Sexually active young people between the ages of 13-16

These clients can only be treated if they are deemed to meet Fraser guidelines (see section 2) and fulfill all the other requirements set out in the PGD. If the client is not deemed to meet Fraser guidelines, parental consent is required before any treatment can be provided.

Confidentiality can only be breached in circumstances where there are concerns regarding the health, safety or welfare of the young person (or others) who would otherwise be at grave risk. Staff should bear in mind that under English Law, someone aged under 16 years cannot give legal consent to sexual intercourse, but the Sexual Offences Act does accept there could be times of legal defense if a person reasonably believes that they were over the age of 16 years.

Sexually active young people under 18 and over 16

These clients should all receive treatment assuming they fulfill the requirements set out in the PGD. Although meeting Fraser guidelines is a legal requirement with clients under the age of 16 it should be noted that clients over 16 must also be competent to understand the treatment that they are to receive. Although sexual activity in itself is no longer an offence over the age of 16, young people under the age of 18 are still offered the protection of Child Protection procedures. Considerations for sharing information are the same as those stated above for 13-16 year olds, and should be done if it is the best interests of the child.

4.0 Useful contact details

Camden multi agency safeguarding hub (MASH) team
020 7974 3317

Camden emergency duty team (out of hours)
020 7974 4444

Other
NSPCC Child Protection Hotline
0808 800 5000 (24 hours)

5.0 Accreditation checklist

Only accredited pharmacists are able to provide EHC for free to eligible clients (aged 13 years to under 25 years) at an accredited pharmacy commissioned to provide this service. An approved pharmacy is required to sign an overarching Service Level Agreement (SLA) which applies to both premises and individuals working at said premises.

An accredited pharmacist must be able to satisfy the criteria below. Evidence of this must be submitted to the officers named below and confirmation that the evidence is sufficient and the pharmacist is accredited must be received prior to operating under the Camden and Islington EHC scheme.

Certificates confirming completion of the following Centre for Pharmacy Postgraduate Education (CPPE) distance learning packs/workshops: <ul style="list-style-type: none"> • Emergency Contraception • Safeguarding children and vulnerable adults (workshop or Level 2 e-assessment) • Dealing with difficult discussions
Signed EHC PGDs
A suitable private area for consultation with clients is available.
The premises from which the service will be delivered is open at least 6 days a week and an EHC accredited healthcare professional is available during the stated opening times to deliver EHC.
Medicines counter staff are trained to refer each request for emergency contraception to accredited pharmacists and are updated on accreditation status of pharmacists.
There is window space to allow for this scheme to be advertised.
Provision of advice and information on sexual health and local sexual health services to young people accessing the service.
The prospective accredited pharmacist agrees to work in partnership with local services and departments involved in reducing unplanned conceptions, in line with sexual and reproductive health agendas. Client confidentiality must be maintained.

I certify that I have satisfied the criteria above and the evidence submitted is valid

Signature Date.....

Name of Pharmacist(s) applying for accreditation.....

Name of Community Pharmacy.....

Address of Community Pharmacy.....

6.0 Emergency Hormone Contraception: confidentiality statement

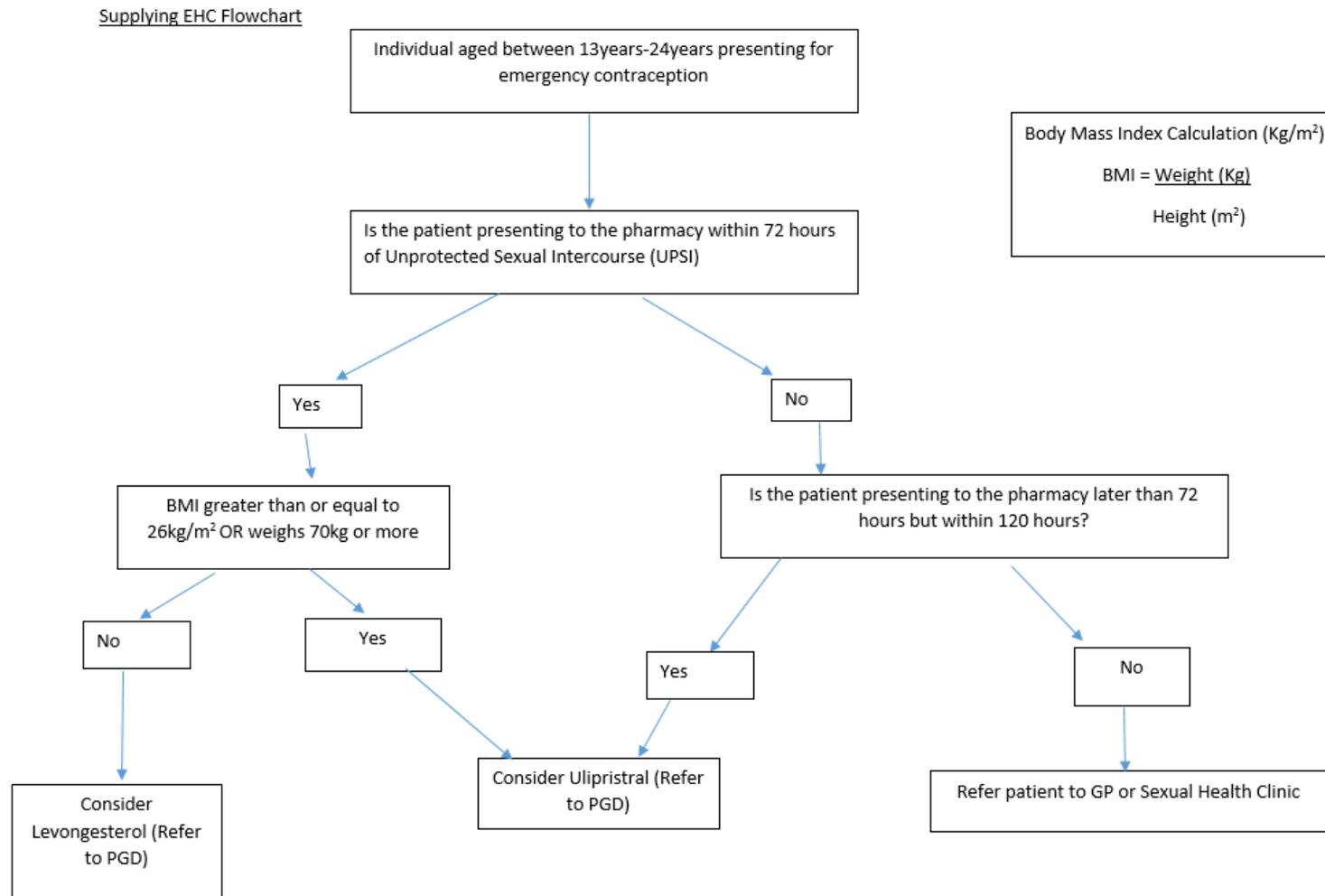
You'll be asked some questions to make sure that the emergency contraception is safe and suitable for you.

The information you give is confidential, which means we don't share information about your visit with anyone else for example parents, teachers, youth workers or GP.

In exceptional circumstances, for example if you or friends are in serious danger or we are worried about your safety, we may have to speak to other professionals in order to help protect you. We would always try to discuss this and any concerns about your welfare with you first.

Please ask the pharmacist if you would like more information.

7.0 Medication provision flowchart





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**PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY
OF LEVONORGESTREL 1.5mg
EMERGENCY CONTRACEPTION (LNG-EC) BY
COMMUNITY PHARMACISTS WORKING IN A COMMUNITY
PHARMACY contracted by Camden or Islington Local
Authority**

ALWAYS REFER TO THE ACCOMPANYING SLA

Version Number 1.4

Change History	
Version and Date	Change details
Version 1.2	New template. Updated SPC/BNF/NICE and other references Minor changes to text Amendments in line with FSRH guidelines (2014)
Version 1.3 May 2017	Amendments to text highlighted in blue Revision in light of UKMEC 2016 guidance and FSRH emergency contraception guidance 2017 Updated Summary of Product Characteristics (SPC) and references Minor editorial changes
Version 1.4 March 2019	Minor changes to text to refer to Ulipristal PGD Removal of off-label double dose use of levonorgestrel

Organisations

Each organisation using this PGD must ensure that it is formally authorised by a pharmacist, a medical lead and a governance lead on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

Community pharmacists

Each community pharmacist using this PGD must ensure that it is formally authorised i.e. signed by a pharmacist, medical lead and governance lead of the commissioning organisation which has legal authority to do so, ensuring that this document meets legal requirements for a PGD.

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LONDON CONTRACEPTION AND SEXUAL HEALTH PATIENT GROUP DIRECTION (PGD) TEMPLATE

PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

This PGD must only be used by registered community pharmacists who have been named and authorised to do so. This will be a locally agreed arrangement between the commissioner and the provider.

The most recent and in date final signed version of the PGD must be used.

Pharmacists are responsible and accountable for ensuring that they work under the relevant PGD and correct Service Specification applicable to the area, and commissioner, where they are working.

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**LONDON CONTRACEPTION AND SEXUAL HEALTH
PATIENT GROUP DIRECTION (PGD) TEMPLATE**

PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

DRUG NAME /STRENGTH/FORM Levonorgestrel 1.5mg tablet

CLINICAL CONDITION TO WHICH THIS DIRECTION APPLIES	<ul style="list-style-type: none"> Emergency hormonal contraception (EHC) within 72 hours of unprotected sexual intercourse (UPSI) or failed contraception
INCLUSION CRITERIA	<ul style="list-style-type: none"> Any female individual aged 13 years – 24 years presenting for emergency contraception within 72 hours of unprotected sexual intercourse (UPSI) or failed contraceptive method and who has no contraindications to the medication For choice of emergency contraceptive method please refer to FSRH emergency contraception decision making algorithm (see https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/) The individual must be able to give informed consent to treatment
EXCLUSION CRITERIA	<p>Personal Characteristics & Reproductive History</p> <ul style="list-style-type: none"> Known or suspected pregnancy (NB 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) One or more episodes of UPSI or compromised contraception during current cycle <ul style="list-style-type: none"> Individual under 16 years of age and assessed as not competent using Fraser guidelines Individual over 16 years of age and over and assessed as not competent to consent Known hypersensitivity to any constituent of the LNG-EC More than 72 hours since this episode of unprotected sexual intercourse Less than 21 days following childbirth

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PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

	<ul style="list-style-type: none"> • Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease • Less than 5 days following ingestion of ulipristal emergency contraception (UPA-EC) • If patient has severe hepatic dysfunction • Acute porphyria • Patients taking ciclosporin (may increase risk of ciclosporin toxicity)
CAUTIONS (INCLUDING ANY ACTION TO BE TAKEN)	<ul style="list-style-type: none"> • Refer to the current Summary of Product Characteristics for full information on special warnings and precautions for use • Emergency post coital intrauterine device (Cu-IUD) should always be considered as a more effective alternative when emergency contraception is required • In an instance where the Cu-IUD is appropriate and acceptable, continue to supply and refer to appropriate health service provider • Ulipristal emergency contraception (UPA-EC) is more effective than LNG-EC • Consider ulipristal if the individual presents in the five days leading up to expected day of ovulation • Consider UPA-EC if individual has a BMI of $\geq 26\text{kg/m}^2$ or weighs 70kg or more. See Ulipristal PGD. • If under 13 years of age follow local safeguarding policy • If individual vomits within three hours from ingestion, a repeat dose may be given • The dose may be repeated more than once in the same menstrual cycle should the need occur • If community pharmacist has any clinical concerns, discuss with appropriate health service provider • Interacting medicines (not enzyme inducers) –see current British National Formulary (BNF)

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PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

	<ul style="list-style-type: none"> • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them, see dose/frequency section •
ACTION IF EXCLUDED	<ul style="list-style-type: none"> • Refer to appropriate health service provider • Discuss /offer alternative emergency contraceptive method • Document all actions taken
ACTION IF PATIENT DECLINES TREATMENT	<ul style="list-style-type: none"> • Record the refusal in the relevant patient record • Signpost/refer to appropriate health service provider with information about further options • Discuss /offer alternative emergency contraceptive method • Document all actions taken

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PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

DRUG DETAILS Levonorgestrel 1.5mg tablet

NAME, FORM & STRENGTH OF MEDICINE	Levonorgestrel 1.5mg tablet
ROUTE/METHOD	Oral
LEGAL CATEGORY	Prescription Only Medicine(POM)/Pharmacy Only Medicine (P)
USE OUTSIDE THE TERMS OF THE MARKETING AUTHORISATION	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC) •
QUANTITY	Original pack of one tablet (1.5mg levongesterol) (or two original packs (3mg levongesterol) if taking enzyme inducing medication)
DOSAGE/FREQUENCY	<ul style="list-style-type: none"> • levongesterol 1.5mg tablet to be taken within 72 hours of UPSI • Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbance of the cycle. <p>Dose for those individuals taking enzyme inducing medications or herbal products</p> <ul style="list-style-type: none"> • An individual who requests levonorgestrel whilst using enzyme –inducing drugs or within four weeks of stopping them, should be advised to take a total of 3 mg levonorgestrel (two 1.5mg tablets) as a single dose. Advise the patient this is based on evidence but on expert judgement of balance of risks and benefits <p>•</p>
DURATION OF TREATMENT	Single dose
MAXIMUM OR MINIMUM TREATMENT PERIOD	Single dose

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PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

<p>SIDE EFFECTS</p> <p>Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. Patients should be actively encouraged to report any suspected adverse reaction, particularly to black triangle medicines.</p>	<p>Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for further information</p> <p>This list may not represent all reported side effects of this medicine</p> <p>Common side effects</p> <ul style="list-style-type: none"> • Nausea • Low abdominal pain • Fatigue • Dizziness • Headache • Diarrhoea/vomiting • Breast tenderness <p>Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next menstrual period within seven days of the expected time.</p> <p>In the event of untoward or unexpected adverse reactions:</p> <ul style="list-style-type: none"> • If necessary seek appropriate emergency advice and assistance • Document in the individual's medical record. • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk <p>The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.</p>
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<p>ADVICE TO INDIVIDUAL</p>	<ul style="list-style-type: none"> • Provide Manufacturer's Patient Information Leaflet (PIL) and discuss
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PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

	<ul style="list-style-type: none"> • Explain mode of action, side effects, and benefits of the medicine • Advise that the medicine should be taken immediately • Explain that the Cu-IUD is considered a more effective method of emergency contraception and signpost to an appropriate healthcare provider after supply of LNG-EC, where appropriate and acceptable • Advise about the risks of the medication including failure rates and serious side effects and actions to be taken • Advise that oral EC is ineffective if given after ovulation • Advise on what to do if vomits within three hours • Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/sites/default/files/emergency-contraception-your-guide.pdf • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections • Discuss ongoing contraception and provide written advice on all methods • Advise a pregnancy test three weeks after treatment especially if period is delayed or abnormal, or if using hormonal contraception which may affect bleeding pattern • Ensure the individual has contact details of local contraceptive /sexual health services • Levonogesterol is secreted into breastmilk. Potential exposure of an infant to levonogesterol can be reduced if the breastfeeding woman takes the tablet immediately after feeding and avoids nursing at least 8 hours following levonogesterol administration
FOLLOW UP	<ul style="list-style-type: none"> • Individual to attend appropriate health service provider if period is delayed, absent or abnormal or if she is otherwise concerned • Individual to attend appropriate health service provider for ongoing contraception and STI screening as required • Pregnancy test as required (see advice to individual)

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LONDON CONTRACEPTION AND SEXUAL HEALTH PATIENT GROUP DIRECTION (PGD) TEMPLATE

PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

RECORDS	<p>The authorised community pharmacist must ensure the following is documented in the individual's medical record:</p> <ul style="list-style-type: none"> • Individual's name, address and date of birth • GP contact details if registered • Attendance date • Reason for attendance • Relevant past and present medical history, including drug history • Any known allergy • The consent of the individual • If individual is under 13 years of age, record action taken • If individual is under 16 years of age document competency, using Fraser guidelines • If individual is 16 years of age and over and not competent, record action taken • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply is by using a PGD • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any supply outside the terms of the product marketing authorisation • Record the name/brand, dose of the medication and quantity supplied • Record batch number and expiry date according to local policy or national guidelines • Any referral arrangements • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the community pharmacist supplying the medicine
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REFERENCES	<p>All links correct at the time of publication (May 2017)</p> <p>Manufacturers' Summaries of Product Characteristics</p> <ul style="list-style-type: none"> • Levonelle 1500 microgram tablet; Summary of Product Characteristics Updated -15.11.2016 Bayer plc; Accessed 27.02.2017 https://www.medicines.org.uk/emc/medicine/16887/SPC/Levonelle+1500+microgram+tablet/ • Upostelle 1500 microgram tablet :Summary of Product Characteristics Updated 06.01.2017 Consilient Health Ltd: Accessed 27.02.2017 https://www.medicines.org.uk/emc/medicine/28337 • Levonelle One Step: Summary of Product Characteristics Updated 06.01.2015 Bayer plc Accessed 27.02.2017 https://www.medicines.org.uk/emc/medicine/15227 • Boots Emergency Contraceptive 1.5mg tablet: Summary of Product Characteristics Updated 14.02.2017 Accessed 27.02.2017 http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1489730898925.pdf • Isteranda 1.5 mg levonorgestrel. Summary of Product Characteristics Updated 24.11.2016 Sandoz Limited: Accessed 27.02.2017 http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1489124848980.pdf • Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <http://www.medicinescomplete.com accessed 16.03.2017 • National Institute for Health and Care Excellence (2013). Patient Group Directions. Medicines Practice Guidelines 2 http://www.nice.org.uk/guidance/MPG2 accessed 16.03.2017 • Faculty of Sexual and Reproductive Healthcare (2017) Emergency contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ • Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for contraceptive use http://www.fsrh.org/ukmec accessed 16.03.2017 • Faculty of Sexual and Reproductive Healthcare (2017) Drug Interactions with hormonal contraception http://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal • Faculty of Sexual and Reproductive Healthcare (2017) Quick Starting Contraception http://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/
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STAFF CHARACTERISTICS

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<p>The named community pharmacist authorised to supply and/or administer medications under the PGD must meet the following criteria:</p>	<p>THE COMMUNITY PHARMACIST MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT</p> <p>Registration The community pharmacist must be registered with the General Pharmaceutical Council (GPhC)</p> <p>Specialist qualifications and competencies</p> <ul style="list-style-type: none"> • Has successfully completed the CPPE PGD e-learning programme or can provide evidence that they have achieved the competency levels specified in NICE Competency Framework for Health Professionals using Patient Group Directions http://www.nice.uk/mpc/goodpracticeguidance/GPG2.jsp • Has had the training which enables the pharmacist to make a clinical assessment in order to establish the contraceptive need and supply the medicine according to this PGD • Can satisfy the requirements of self declaration of qualifications and competence to deliver emergency contraceptive services according to the CPPE Programme for <ul style="list-style-type: none"> ○ Emergency Hormonal Contraception ○ Safeguarding children and vulnerable adults <p>or</p> <ul style="list-style-type: none"> • Can provide evidence of competencies achieved through other local face-to-face training which delivers the equivalent knowledge. <p>and</p> <ul style="list-style-type: none"> • Pharmacists must ensure that the pharmacy where they are providing the service is contracted for this service • Have a current contract of employment with a Camden or Islington Community Pharmacy <p>Maintenance of competencies</p> <ul style="list-style-type: none"> • Has demonstrated that they are competent to provide the service • The pharmacist should ensure she/he is aware of any changes to the recommendations for this medication • Is familiar with current FSRH clinical guidelines on emergency contraception
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An up to date list and signatures of registered community pharmacists who are authorised to practise under this PGD is kept in _____ by _____
Practitioners not listed are not authorised to practise under this PGD

PGD DEVELOPMENT GROUP

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Date PGD template comes into effect:	09/05/2017
Review date	09/11/2019 or earlier in the light of significant changes in best practice
Expiry date:	09/05/2020

This template was peer reviewed and ratified by London Contraception and Sexual Health PGD Working Group:

NAME/ROLE	POSITION	DATE
Kathy French Chair - Working Group	Independent Nurse Advisor SRHC, Project Lead	24/04/2017
Angela Bussey Advisor - Working Group	Principal Pharmacist Medicines Information Projects. Guy's and St Thomas' NHS Foundation Trust.	09/05/2017
Medical Lead Dr Sarah Pillai	Lead Associate Specialist, Contraception and Sexual Health Service, Central London Community Healthcare NHS Trust	24/04/2017
Lead Pharmacist Sandra Wolper	Associate Director for Specialist Pharmacy Service Hounslow and Richmond NHS Trust	24/04/2017
Lead Nurse Sandra Bennett	Lead Nurse, Integrated Sexual Health Services, Barts Health NHS Trust	24/04/2017

The PGD template is not legally valid until it has had the relevant organisational approval.

See next page

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ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

The PGD is not legally valid until it has had the relevant organisational authorisations. To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the authorising organisation. Complete details below or use format agreed according to local policy.

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Dominic Roberts Clinical Director and Medicines Safety Officer, Islington CCG		29.3.2019
Senior pharmacist	Iman Shaban Deputy Head of Medicines Management, Islington CCG		28/03/2019
Person signing on behalf of <u>authorising body</u>	Dr Julie Billett, Director of Public Health, Camden and Islington Local Authorities		29/03/2019

It is the responsibility of the authorising organisation to ensure that all legal and governance requirements are met.

To meet legal requirements, organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners to this template. This varies according to local policy and how the service is managed but this should be a signature list or an individual agreement.

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 the General Pharmaceutical Council, Standards of Conduct Ethics and Performance. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medicines listed only in accordance with the PGD.

Pharmacists are responsible and accountable for ensuring that they work under the relevant PGD and correct Service Specification applicable to the area, and commissioner, where they are working. (See page one)

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This Patient Group Direction must be agreed to and the individual authorisation register signed by all pharmacists involved in its use. The CCG Head of Medicines Management should hold the original signed copy. The PGD must be easily accessible in the clinical setting.	
Organisations	London Borough of Camden London Borough of Islington Camden Clinical Commissioning Group Islington Clinical Commissioning Group

Authorisation. To be completed by the approved pharmacist:	
I have received, read and fully understand the following: <ul style="list-style-type: none"> • The relevant Patient Group Direction • I have undertaken training which approved practitioners must undertake before being authorised to supply levonorgestrel under the relevant Patient Group Direction • I agree to act as an approved practitioner within the terms of the Patient Group Direction and to supply accordingly • I understand that by agreeing to act as an approved practitioner under Patient Group Directions I am adjusting my scope of professional practice 	
Name:	Name of Pharmacy:
GPhC number:	Address of Pharmacy:
Signature:	Date:

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**PATIENT GROUP DIRECTION (PGD)
FOR THE SUPPLY OF ULIPRISTAL ACETATE 30MG
EMERGENCY CONTRACEPTION (UPA-EC) BY COMMUNITY
PHARMACIST WORKING IN A COMMUNITY PHARMACY
contracted by Camden or Islington Local Authority**

Version Number 1.5

Change History	
Version and Date	Change details
Version 1.2	Legal status of this medicine changed in January 2015 to P. PGD amended so that either P or POM can be supplied Amended to reflect that use in individuals under 18 is licensed. There are no other unlicensed uses Spelling and minor changes in blue Changes in light of Faculty of Sexual and Reproductive Health (FSRH) 2015 guidance on quick starting hormonal contraception
Version 1.3	Minor amendment, change to clarify additional precautions when (re)starting hormonal contraception
Version 1.4 May 2017	Amendments to text highlighted in blue Revision in light of UKMEC 2016 guidance and FSRH emergency contraception guidance 2017 Updated Summary of Product Characteristics (SPC) and references Minor editorial changes
Version 1.5 March 2019	To include community pharmacists

Each organisation using this PGD must ensure that it is formally authorised by a pharmacist, a medical lead and a governance lead on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

Community pharmacists

Each community pharmacist using this PGD must ensure that it is formally authorised i.e. signed by a pharmacist, medical lead and governance lead of the commissioning organisation which has legal authority to do so, ensuring that this document meets legal requirements for a PGD.

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This PGD must only be used by registered community pharmacists who have been named and authorised to do so. This will be a locally agreed arrangement between the commissioner and the provider.

The most recent and in date final signed version of the PGD must be used.

Pharmacists are responsible and accountable for ensuring that they work under the relevant PGD and correct Service Specification applicable to the area, and commissioner, where they are working.

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**PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-
EC) BY REGISTERED COMMUNITY PHARMACISTS**

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DRUG NAME /STRENGTH/FORM Ulipristal acetate 30 mg tablet

CLINICAL CONDITION TO WHICH THIS DIRECTION APPLIES	<ul style="list-style-type: none"> Emergency contraception
INCLUSION CRITERIA	<ul style="list-style-type: none"> Female individual aged 13 years – 24 years presenting for emergency contraception following unprotected sexual intercourse (UPSI) or failed contraceptive method and who has no contraindications to the medication For choice of emergency contraceptive method please refer to FSRH emergency contraception decision making algorithm (see https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/) The individual must be able to give informed consent to treatment
EXCLUSION CRITERIA	<p>Personal Characteristics & Reproductive History</p> <ul style="list-style-type: none"> Known or suspected pregnancy (NB 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) Individual under 16 years of age and assessed as not competent using Fraser guidelines Individual 16 years of age and over and assessed as not competent to consent Known hypersensitivity to any constituent of the UPA tablet (refer to the summary of product characteristics for full list of excipients) More than 120 hours since this episode of UPSI Less than 21 days following childbirth Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease Severe hepatic dysfunction <p>Other Conditions</p> <ul style="list-style-type: none"> Use in women with severe asthma treated by oral glucocorticoid is not recommended Individual wishes to see a doctor <p>Interacting medicines – see current BNF for interactions</p> <ul style="list-style-type: none"> Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them

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	<ul style="list-style-type: none"> Individual currently using drugs that increase gastric pH (e.g. antacids, histamine H2 antagonists and proton pump inhibitors)
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CAUTIONS (INCLUDING ANY ACTION TO BE TAKEN)	<ul style="list-style-type: none"> Refer to the current Summary of Product Characteristics for full information on special warnings and precautions for use Emergency post coital intrauterine device (Cu-IUD) should always be considered as a more effective alternative when emergency contraception is required In an instance where the Cu-IUD is appropriate and acceptable, continue to supply and refer to appropriate health service provider If individual is under 13 years of age follow local safeguarding policy Breastfeeding is not recommended for 7 days following ingestion of UPA, advise the individual to express and discard the breast milk during that time If the individual vomits within three hours from ingestion, a further dose may be given The effectiveness of UPA-EC may be reduced if a woman takes progestogen (including levonorgestrel emergency contraception LNG-EC) in the week prior to and five days following UPA-EC. Consider Cu-IUD or LNG-EC in this circumstance It is recommended that hormonal contraception should not be used for five days after UPA, then (re)started. A barrier contraceptive should be used for a further 7 days (9 days for Qlaira®) if using combined hormonal contraception or 48 hours for oral progestogen-only contraception If UPSI occurs within five days of UPA-EC, Cu-IUD should be offered if appropriate, or a further dose can be given. Discuss with appropriate doctor/independent non-medical prescriber any medical condition or medication of which the nurse/midwife is unsure
ACTION IF EXCLUDED	<ul style="list-style-type: none"> Refer to appropriate health service provider prescriber Discuss/offer alternative emergency contraceptive method Document all actions taken
ACTION IF PATIENT DECLINES TREATMENT	<ul style="list-style-type: none"> Record refusal in the clinical record Refer to appropriate doctor/independent non-medical prescriber Discuss/offer alternative emergency contraceptive method Document all actions taken

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DRUG DETAILS	
NAME, FORM & STRENGTH OF MEDICINE	Ulipristal acetate 30mg tablet
ROUTE/METHOD	Oral
LEGAL CATEGORY	Pharmacy Only Medicine (P)
USE OUTSIDE THE TERMS OF THE MARKETING AUTHORISATION	<p>Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC)</p> <p>This PGD includes unlicensed use in the following conditions:</p> <ul style="list-style-type: none"> • If UPSI occurs within five days of UPA-EC, a further dose can be given
QUANTITY	Original pack of one tablet
DOSAGE/FREQUENCY	Single dose Can be repeated within the same menstrual cycle if required
DURATION OF TREATMENT	Single dose
MAXIMUM OR MINIMUM TREATMENT PERIOD	Single dose
SIDE EFFECTS Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. Patients should be actively encouraged to report any suspected adverse reaction, particularly to black triangle medicines.	<p>Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information</p> <p>This list may not represent all reported side effects of this medicine</p> <p>Common side effects</p> <ul style="list-style-type: none"> • Gastro-intestinal disturbances (including nausea, vomiting) • Abdominal pain and discomfort • Dizziness • Headache • Fatigue • Mood changes • Breast tenderness • Dysmenorrhoea • Pelvic Pain • Myalgia • Back pain <p>See next page</p>

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SIDE EFFECTS continued	<p>Continued from previous page</p> <p>Uncommon side effects</p> <ul style="list-style-type: none"> • Acne • Libido change • Migraine <p>In the event of untoward or unexpected adverse reactions:</p> <ul style="list-style-type: none"> • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent non-medical prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk <p>The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.</p>
ADVICE TO INDIVIDUAL	<ul style="list-style-type: none"> • Provide Manufacturer's Patient Information Leaflet (PIL) and discuss • Explain mode of action, side effects, and benefits of the medicine • Advise that the medicine should be taken immediately • Explain that the Cu-IUD is considered a more effective method of emergency contraception and refer to an appropriate healthcare provider after supply of UPA-EC, where appropriate and acceptable • Advise about the risks of the medication including failure rates and serious side effects and actions taken • Advise that oral EC may be less effective if the individual has a higher weight or BMI • Advise that oral EC is ineffective if given after ovulation • Advise on what to do if vomits within three hours • Breastfeeding is not recommended for 7 days following ingestion of UPA-EC, advise the individual to express and discard the breast milk during this time in order to stimulate lactation • Women using hormonal contraception must be aware that there may be an interaction with their current form of contraception and it is recommended that they do not take their hormonal contraception for five days after UPA-EC, then (re)start and use barrier contraception according to method guidance. <p>See next page</p>

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ADVICE TO INDIVIDUAL continued	<p>Continued from previous page</p> <ul style="list-style-type: none"> • Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/sites/default/files/emergency-contraception-your-guide.pdf • Offer condoms and advise on safer sex practices and possible need for screening for sexually transmitted infections • Discuss and offer ongoing contraception and provide written advice on all methods • Advise the patient that she could still become pregnant. In case the next menstrual period is more than 7 days late, if the menstrual period is abnormal in character or if there are symptoms suggestive of pregnancy or in case of doubt, a pregnancy test should be performed and women should seek medical advice. • Ensure the individual has contact details of local contraceptive/sexual health services
FOLLOW UP	<ul style="list-style-type: none"> • Individual to return if period is delayed, absent or abnormal or if she is otherwise concerned • Pregnancy test as required (see advice to individual)

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RECORDS	<p>The authorised community pharmacist must ensure the following is documented in the clinical record:</p> <ul style="list-style-type: none"> • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history • Any known allergy • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply is by using a PGD • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any supply outside the terms of the product marketing authorisation • The consent of the individual • If individual is under 13 years of age, record action taken • If individual is under 16 years of age document competency using Fraser guidelines • If individual is 16 years of age and over and not competent to consent, record action taken • Record the name/brand, dose of the medication and quantity supplied • Record batch number and expiry date according to local policy or national guidelines • Any referral arrangements • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the community pharmacist supplying the medicine
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REFERENCES	<p>All links correct at the time of publication (May 2017)</p> <ul style="list-style-type: none"> • Manufacturer's Summary of Product Characteristics ellaOne. HRA Pharma UK and Ireland https://www.medicines.org.uk/emc/medicine/22280/SPC/ellaOne+30+mg/ Updated 30.01.2017 accessed 03 05.2017 • Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <http://www.medicinescomplete.com accessed 03 05.2017 • National Institute for Health and Care Excellence (2013). Patient Group Directions. Medicines Practice Guidelines 2 http://www.nice.org.uk/guidance/MPG2 accessed 03.05.2017 • Faculty of Sexual and Reproductive Healthcare (2017) Emergency contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ • Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for contraceptive use http://www.fsrh.org/ukmec accessed 16.03.2017 • Faculty of Sexual and Reproductive Healthcare (2017) Drug Interactions with hormonal contraception http://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal • Faculty of Sexual and Reproductive Healthcare (2017) Quick Starting Contraception http://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/
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STAFF CHARACTERISTICS

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LONDON CONTRACEPTION AND SEXUAL HEALTH PATIENT GROUP DIRECTION (PGD) TEMPLATE

PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

<p>The named community pharmacist authorised to supply and/or administer medications under the PGD must meet the following criteria:</p>	<p>THE COMMUNITY PHARMACIST MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT</p> <p>Registration The community pharmacist must be registered with the General Pharmaceutical Council (GPhC)</p> <p>Specialist qualifications and competencies</p> <ul style="list-style-type: none"> • Has successfully completed the CPPE PGD e-learning programme or can provide evidence that they have achieved the competency levels specified in NICE Competency Framework for Health Professionals using Patient Group Directions http://www.nice.uk/mpc/goodpracticeguidance/GPG2.jsp • Has had the training which enables the pharmacist to make a clinical assessment in order to establish the contraceptive need and supply the medicine according to this PGD • Can satisfy the requirements of self-declaration of qualifications and competence to deliver emergency contraceptive services according to the CPPE Programme for <ul style="list-style-type: none"> ○ Emergency Hormonal Contraception ○ Safeguarding children and vulnerable adults <p>or</p> <ul style="list-style-type: none"> • Can provide evidence of competencies achieved through other local training which delivers the equivalent knowledge. <p>and</p> <ul style="list-style-type: none"> • Pharmacists must ensure that the pharmacy where they are providing the service is contracted for this service • Have a current contract of employment with a Camden or Islington Community Pharmacy <p>Maintenance of competencies</p> <ul style="list-style-type: none"> • Has demonstrated that they are competent to provide the service • The pharmacist should ensure she/he is aware of any changes to the recommendations for this medication <p>Is familiar with current FSRH clinical guidelines on emergency contraception</p>
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An up to date list and signatures of registered practitioners who are authorised to practice under this PGD is kept in the PGD central folder by the Nurse Manager in Brook London

Practitioners not listed are not authorised to practice under this PGD.

PGD DEVELOPMENT GROUP

Version No: 1.4	Expiry date: 31/03/2020
Approving Organisation Name: London Borough of Camden and London Borough of Islington.	
Clinical Governance approval: Dr Julie Billett	Reference Number : TBC
Date of authorisation: 29/03/2019	Page 35 of 39

**LONDON CONTRACEPTION AND SEXUAL HEALTH
PATIENT GROUP DIRECTION (PGD) TEMPLATE**

PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

Date PGD template comes into effect:	09/05/2017
Review date	09/11/2019 or earlier in the light of significant changes in best practice
Expiry date:	09/05/2020

This template was peer reviewed and ratified by London Contraception and Sexual Health PGD Working Group:

NAME/ROLE	POSITION	DATE
Kathy French Chair - Working Group	Independent Nurse Advisor SRHC Project Lead	24/04/2017
Angela Bussey Advisor - Working Group	Principal Pharmacist Medicines Information Projects. Guy's and St Thomas' NHS Foundation Trust.	09/05/2017
Lead Medical Dr Sarah Pillai	Associate Specialist, Contraception and Sexual Health Service, Central London Community Healthcare NHS Trust	24/04/2017
Lead Pharmacist Sandra Wolper	Associate Director for Specialist Pharmacy Service, Hounslow and Richmond NHS Trust	24/04/2017
Lead Nurse Sandra Bennett	Lead Nurse, Integrated Sexual Health Services, Barts Health NHS Trust	24/04/2017

The PGD template is not legally valid until it has had the relevant organisational approval.

See next page

ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

This page may be deleted if replaced with a format agreed according to local PGD policy with relevant approvals and authorisation.

The PGD is not legally valid until it has had the relevant organisational authorisations. To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the person signing on behalf of the authorising organisation.

Version No: 1.4	Expiry date: 31/03/2020
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**LONDON CONTRACEPTION AND SEXUAL HEALTH
PATIENT GROUP DIRECTION (PGD) TEMPLATE**

PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

You may either complete details below or delete and use a format agreed according to local PGD policy which complies with PGD legislation and NICE MPG2 PGD 2013.

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Dominic Roberts Clinical Director and Medicines Safety Officer, Islington CCG		29.3.19
Senior pharmacist	Iman Shaban Deputy Head of Medicines Management, Islington CCG		28.03.19
Person signing on behalf of <u>authorising body</u>	Julie Billett, Director of Public Health, London Borough of Islington and London Borough of Camden		29.03.19

It is the responsibility of the authorising organisation to ensure that all legal and governance requirements for authorising the PGD are met.

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

To meet legal requirements, organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy and how the service is managed but this should be a signature list or an individual agreement.

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 own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medicines listed only in accordance with the PGD.

ORGANISATIONS MAY ALSO ADD:

- Local training and competency assessment documentation.
- Other supporting local guidance or information.
- Links to local PGD Policy and other supporting guidance.

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**LONDON CONTRACEPTION AND SEXUAL HEALTH
PATIENT GROUP DIRECTION (PGD) TEMPLATE**

**PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-
EC) BY REGISTERED COMMUNITY PHARMACISTS**

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**LONDON CONTRACEPTION AND SEXUAL HEALTH
PATIENT GROUP DIRECTION (PGD) TEMPLATE**

PGD FOR THE SUPPLY OF LEVONORGESTREL 1.5MG EMERGENCY CONTRACEPTION (LNG-EC) BY REGISTERED COMMUNITY PHARMACISTS

This Patient Group Direction must be agreed to and the individual authorisation register signed by all pharmacists involved in its use. The CCG Head of Medicines Management should hold the original signed copy. The PGD must be easily accessible in the clinical setting.	
Organisations	London Borough of Camden London Borough of Islington Camden Clinical Commissioning Group Islington Clinical Commissioning Group

Authorisation. To be completed by the approved pharmacist:	
I have received, read and fully understand the following: <ul style="list-style-type: none"> • The relevant Patient Group Direction • I have undertaken training which approved practitioners must undertake before being authorised to supply levonorgestrel under the relevant Patient Group Direction • I agree to act as an approved practitioner within the terms of the Patient Group Direction and to supply accordingly • I understand that by agreeing to act as an approved practitioner under Patient Group Directions I am adjusting my scope of professional practice 	
Name:	Name of Pharmacy:
GPhC number:	Address of Pharmacy:
Signature:	Date:

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