POLICY DOCUMENT

Patient Group Direction for the Supply and administration of Ulipristal acetate (UPA- EC) for Emergency Contraception by Community Pharmacists

Approved by:	**Leicestershire and Rutland County Councils Public Health Departmental Management Team**
Commencement date:	**1 July 2019**
Expiry Date:	**30 June 2022**
Directorate responsible for Review:	**Public Health (Leicestershire and Rutland County Councils)**
PGD Number:	**PGDLR006**

Due Regard

The Councils' commitment to equality means that this PGD has been screened in relation to paying due regard to the general duty of the Equality Act 2010 to eliminate unlawful discrimination, harassment, victimisation; advance equality of opportunity and foster good relations.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

It is judged that it is not proportionate (equality relevant) in respect of this PGD as it specifically enables identified registered pharmacists to supply and administer medicines in accordance with national guidelines. Due regard has been given in respect of accessibility (larger print, Braille etc), including the provision of information or advice in an alternative language and consideration of patient carers and family members for support.

Patient Group Direction (PGD) for the supply of Ulipristal acetate (UPA) for Emergency Contraception by designated community pharmacists across Leicester, Leicestershire and Rutland. This PGD is to be used in conjunction with the PGD for the supply of levonorgestrel (LNG) Ref: PGDLR007, with LNG supplied only in circumstances where exclusion criteria for UPA apply and LNG inclusion criteria are met.

Premises

From registered pharmacy premises which have been approved for this service by Leicestershire County Council or Rutland County Council.

Staff Characteristics

Qualifications	• Registered Pharmacists currently on the practicing section of the pharmaceutical register held by the General Pharmaceutical Council that have completed the required training for accreditation and competency • Practitioners must hold a current and up to date Enhanced Disclosure and Barring Service check **ALL HEALTHCARE PROFESSIONALS MUST BE AUTHORISED BY NAME UNDER THIS DIRECTION BEFORE USING IT.**
Method of Competency assessment	Pharmacists applying (or re-applying) to be on the Approved Provider List will have declared themselves competent using the CPPE Declaration of Competence for Community Pharmacy Services Emergency Contraception and will undertake to keep themselves up to date. Each Council will approve pharmacies to provide the service in that locality and pharmacy providers, at the request of the commissioner, will be required to provide evidence to confirm that pharmacists have the necessary skills and competencies in accordance with the requirements of the contract. Before commencing the delivery of this service, all providers must have attended at least one face to face local CPPE training event.
Specialist competencies or qualifications	The pharmacist must be competent to assess a client's capacity to understand the nature and purpose of the treatment in order to give or refuse consent. Evidence of completion of approved CPPE training packages listed below and successful completion of their associated e-assessment. • CPPE's e-learning on Contraception • CPPE's e-learning on Emergency Contraception since January 2019 • CPPE's e-learning on Safeguarding children and vulnerable adults. (e.g. CPPE online competence assessment) on EHC. • The CPPE e-assessments must be completed successfully every 3 years. The practitioner must also attend a local workshop session, organised and delivered by the Integrated Sexual Health service.

Frequency of Competency review	Three yearly
Accountability for competency assessment	Pharmacists will self-declare using the CPPE Declaration of Competence for Community Pharmacy Services – Emergency Contraception
Accountability for staff involved in using the PGD	Pharmacists using the PGD are accountable to the Responsible Pharmacist and the Superintendent Pharmacist of the Pharmacy in which they are providing pharmaceutical services. The Responsible Pharmacist is responsible for the correct implementation of the PGD.
Continuing training & education	The practitioner should be aware of any change to the recommendations for Ulipristal acetate. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice. CPPE e-learning and e-assessment training refresh on Safeguarding children, young people and vulnerable adults module every 3 years; evidenced by satisfactory completion of e-assessment. The practitioner must attend a local workshop session, organised and delivered by the Integrated Sexual Health Service, as a refresh every 3 years.

Referral Arrangements and Audit Trail	
Additional Facilities and Referral Arrangements	The client must always be advised to talk to her GP or Integrated Sexual Health Services across Leicester, Leicestershire and Rutland by way of follow up and to consider future contraceptive requirements, regardless of whether a supply is made. Where the circumstances are outside the PGD, or where there are medical concerns, or if the client wishes it, the client should be: • Considered for Levonorgestrel supply under PGD Ref XXX, if inclusion criteria apply. • Referred to their GP • Referred to Integrated Sexual Health Service clinics using the Client Referral Form. • Referred for urgent care or out of hours services
Records/audit trail	Records should be made on the Client Record Sheet (Appendix 2)

Ongoing Monitoring	
Method of auditing adherence to PGD	Adherence to the PGD will be monitored through the data submissions and mystery shopping/audit exercise
Frequency of audit	Annually
Accountability for audit and monitoring	Respective Consultant lead in Public Health at each local authority

Supply of Ulipristal acetate (UPA-EC) for Emergency Contraception, by designated community pharmacists across, Leicestershire and Rutland.

Clinical Condition	
Indication	Clients presenting to a community pharmacy requesting Emergency Contraception (EC) who, following appropriate assessment, are at risk of pregnancy. (As eligible in relation to inclusion criteria)

Inclusion criteria

- Clients over 16 years of age and under 25 years of age
- Clients under 16 years of age who have been assessed as Fraser competent (see Appendix 3 and cautions on page 10)
- Clients under 16 years of age who have been assessed as not Fraser competent (see Appendix 3 and cautions on page 10)
- Any woman presenting for emergency contraception up to 120 hours (5 days) after Unprotected Sexual Intercourse (UPSI) or failed contraceptive method* where the woman has no contraindications to UPA
- Copper intrauterine device has been discussed.
- Patient who has vomited within 3 hours of taking UPA

PLEASE NOTE THAT THIS IS NOT AN EXHAUSTIVE LIST.

Please also refer to FSRH guidance

https://www.fsrh.org/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

Exclusion criteria

- Any episode of UPSI more than 120 hours prior to presentation
- Has taken progestrogen within the last 7 days (Refer to PGD Ref PGDLR007 to determine if appropriate to supply LNG)
- Pregnancy known
- Client has had a baby in the last 3 weeks (EC not required in these circumstances)
- Breastfeeding and not willing to express milk for 7 days (Refer to PGD Ref PGDLR007 to determine if appropriate to supply LNG)
- Known allergy to constituents of UPA (ellaOne ®) or any of the excipients (refer to Summary of Product Characteristics (SPC)) (Refer to PGD Ref PGDLR007 to determine if appropriate to supply LNG Refer to PGD Ref PGDLR007 to determine if appropriate to supply LNG)
- Concomitant use with emergency contraception containing LNG. (Refer to PGD Ref PGDLR007 to determine if appropriate to supply LNG)
- Clients aged 25 years and over (please consider OTC supply)
- Other Conditions:
  - Severe asthma where treated by oral glucocorticoids
- Taking interacting medicines - See interactions section and BNF, and FSRH Guidelines: https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/

If the client is receiving any concomitant medication or treatment it is the responsibility of the Registered Pharmacist to ensure that treatment with the drug detailed in this PGD is appropriate.

- Women taking enzyme inducing drugs, or within 4 weeks of stopping them: The metabolism of both UPA-EC and LNG-EC is increased during and for 28 days after use of drugs that induce liver enzymes. The clinical relevance of this interaction in terms of potential reduction in effectiveness is unknown although guidance suggests LNG-EC may be considered ((Refer to PGD Ref PGDLR007 to determine if appropriate to supply LNG)

(1) A Cu-IUD should be recommended for women using enzyme-inducing drugs if the criteria for use are met as the Cu-IUD is unaffected by liver enzyme induction..

Examples of enzyme-inducing drugs

Antiepileptics	carbamazepine, eslicarbazepine, oxcarbazepine, phenobarbital, phenyto primidone, rufinamide topiramate
Antibiotics	rifabutin, rifampicin
Antiretrovirals	***Always use the HIV Drug Interaction Checker (www.hiv-druginteractions.org) to identify potential interactions***
Antidepressants	St John's wort
Others	modafinil, bosentan, aprepitant

(2) Griseofulvin-avoid

Action if patient declines or is excluded	Discuss reason for exclusion with client. Clients aged 25 years and over may be eligible to purchase OTC EC. Clients excluded under this PGD may be offered LNG (refer to Levenorgestral PGD ref PGDLR007 for inclusion criteria). If client is also excluded under the LNG PGD, they are to be referred for further assessment to a registered medical practitioner (e.g. their own GP) or the nearest accessible Integrated Sexual Health Service clinic offering contraceptive services. The advice given should be documented in the client's record sheet (and Patient Medication Record if appropriate). If last UPSI was more than 120 hours ago but within 5 days (120 hours) after likely ovulation the client may be suitable for IUCD (intrauterine device) insertion and referral should be made to either the Integrated Sexual Health Services or the patient's own GP in a suitable timeframe to allow this to happen. Note that not all GPs provide an IUD fitting service. Where care is declined by the client, document refusal in client's clinical records. Ensure the client is signposted to different services in the area e.g. Integrated Sexual Health Service Clinic, general practitioner Advise the client that GP practices <u>may</u> provide contraceptive services to patients meeting certain criteria. It is important to warn the client that a delay in starting treatment will compromise its efficacy. **If any doubt about exclusion, telephone the Integrated Sexual Health Services on 0300 1240102 or contact the client's own GP for advice, <u>with the client's consent</u>.**

Cautions/Need for further advice

If in doubt about cautions, refer to or telephone the Integrated Sexual Health Service on 0300 1240102 or contact the client's GP.

Please refer to the current BNF edition for further information.

Cautions (including any relevant action to be taken). See table 1 on page 11 below.

- Under 16 years of age and assessed as not competent using Fraser Guidelines.
- 16 years of age and over and assessed as not competent to consent.
- If under 13 years of age follow local safeguarding policy, using professional judgement to consider supply.
- Emergency post coital intrauterine device (IUCD) should always be considered as a more effective alternative when emergency contraception is required. An IUCD may be fitted up to 5 days after unprotected sexual intercourse or 5 days after expected date of ovulation in that cycle.
- In an instance where the emergency copper bearing IUCD is appropriate and acceptable, continue to supply and signpost to appropriate health service provider.
- 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 individual vomits within three hours from ingestion, a further dose may be given under this PGD.
- If a woman wishes to start or continue using hormonal contraception, she can do so a minimum of 5 days after using UPA. The SPC for UPA advises to use a reliable barrier method until the next menstrual period.
- If community pharmacist has any concerns, discuss with appropriate health service provider.
- Provide written advice on ongoing contraceptive methods

Action if excluded:

- **Do not supply UPA under PGD**
- Discuss reasons for exclusion.
- Decide if inclusion criteria for LNG are met and supply according to the LNG PGD (Reference PGDLR007).
- Discuss alternative methods of contraception and refer to appropriate/preferred health provider as required: Contraceptive and Sexual Health Service tel: 0300 1240102 or make an appointment to with GP.
- Document all actions taken.

Action to be taken if patient declines treatment:

- Discuss reasons for exclusion and alternative methods of emergency contraception e.g. IUCD
- Record the refusal in the relevant patient record
- Refer to appropriate / preferred health provider
- Document all actions taken

Table 1: Cautions and relevant action/advice.

Cautions	Advice/Actions	Comments
Clients aged 13 years or under	• Use of professional judgement to consider supply of UPA as appropriate. (see Appendix 3) • There is a duty to seek further advice and onward referral to address child protection issues. • **The Child Protection Team must be contacted for clients aged 13 or under who present having had sexual intercourse.**	Please see Appendix 5 for referral pathways and contact details.
Clients under 16	• Make assessment in relation to Fraser competence (see Appendix 4), consider safeguarding issues, including sexual exploitation and follow pathway to supply of UPA and/or refer as appropriate.	
Clients under 16 years assessed as NOT Fraser competent	• Use of professional judgement to consider supply of UPA as appropriate. (see Appendix 3) • There is a duty to seek further advice and onward referral to address child protection issues.	Please see Appendix 5 for referral pathways and contact details.
Clients 16 years and above assessed as not competent to consent.	• Use of professional judgement to consider supply of UPA as appropriate. (see Appendix 3) • There is a duty to seek further advice and onward referral to address child protection issues.	Please see Appendix 5 for referral pathways and contact details.
Clients currently taking enzyme inducing drugs or have stopped within the last 28 days.	• Do not supply UPA - refer to LNG PGD ref PGDLR007 to determine eligibility to supply	
Breastfeeding	Advise client: • Not to breastfeed and to express and discard milk for 7 days after taking UPA	If expressing of breastmilk not acceptable to client refer to LNG PGD ref PGDLR007 to determine eligibility to supply
Repeated use in same cycle	Advise client: • She may be pregnant (consider pregnancy test as appropriate) • Repeated use disturbs menstrual cycle • Consider IUCD as preferred alternative • If LNG-EC already taken within last 7 days, do not supply UPA-EC Refer to LNG PGD ref PGDLR007 to determine eligibility to supply.	Please note that there is no epidemiological data to indicate that UPA-EC has an adverse effect on the foetus.
Previous UPSI more than 120 hours earlier within the same cycle and no emergency contraception used.	Consider referral for IUD up to 120 hours from ovulation.	Please note that there is no epidemiological data to indicate that UPA-EC has an adverse effect on the foetus.
Possible pregnancy: • Vague menstrual history • Last menstrual period late/abnormal/different	Consider pregnancy test.	Please note that there is no epidemiological data to indicate UPA has an adverse effect on the foetus.
Severe Hepatic dysfunction	Consider discussion with Integrated Sexual Health Service or GP.	Pregnancy poses a significant risk in this group; therefore expert opinion suggests use UPA
Individuals currently taking drugs that increase gastric pH (e.g. antacids, histamine H2 antagonists and proton pump	Consider supply LNG or IUCD. Refer to LNG PGD ref PGDLR007 to determine eligibility to supply	Drugs that increase gastric pH (including **proton pump inhibitors**, **antacids** and **H2-receptor antagonists)** may reduce absorption and

inhibitors): Potential Interaction- caution required		efficacy of ulipristal acetate (UPA).
Clients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose - galactose malabsorption	Consider discussion with Integrated Sexual Health Service or GP.	Galactose intolerance not listed as caution or contraindication in BNF
Administering oral emergency contraception after ovulation	Advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. An IUCD would be more suitable method in this instance.	It can still be issued in these circumstances in case this is an unusual cycle.

Interactions

See exclusion criteria. (Page 8)

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Supply of Ulipristal acetate (UPA) 30mg **for Emergency Contraception**

Drug Details

Name, form & strength of medicine	**Ulipristal acetate (UPA) 30mg**
Route/Method	Oral administration
Licensing/Use of label	The following are uses outside of the terms of the Product License: •
Dosage	This PGD allows administration outside of the Product License only in the above circumstances. The client must be advised that it is being recommended as an unlicensed indication for UPA not included in the Summary of Product Characteristics (SPC). One Ulipristal acetate (UPA) 30mg tablet should be taken as soon as possible and within 120 hours of UPSI. **The client should be encouraged to take the dose whilst in the pharmacy.**
Frequency	May be given within the 120-hour subject to the cautions timeframe on each occasion, for more than one episode of UPSI within a cycle. **Vomiting** A replacement dose can be provided under this PGD as soon as possible (within the 120 hour post UPSI timeframe) if the client has vomited the first dose within 3 hours
Duration of treatment	Single dose
Maximum or minimum treatment period	Single dose per episode
Quantity to supply/administer	1 x 30mg Ulipristal acetate (UPA) 30mg l tablet – as a single dose *The client should be encouraged to take the dose whilst in the pharmacy.*
Action to take if drug interactions identified	Please read cautions on pages 10 and 11 and check BNF and SPC.

Side effects	Always refer to the current BNF and Summary of Product Characteristics (SPC) available from: www.medicines.org.uk. The most common adverse effects are: • Nausea • Vomiting • Breast tenderness • Headache • Dizziness • Fatigue Temporary disturbance of menstrual bleeding pattern (if menstrual bleed is more than 7 days overdue, pregnancy should be excluded (by taking a pregnancy test)) Advise client to contact the Integrated Sexual Health Services across Leicester, Leicestershire & Rutland or their own GP if they experience any adverse effects (see Appendix 5 for contact details). Use the Yellow Card system to report adverse drug reactions (ADRs) directly to the Medicines and Healthcare Products Regulatory Agency (MHRA). Yellow cards (and guidance) are available in the back of the BNF or obtained via Freephone 0800 7316789 (10am-2pm Mon-Friday) or online at www.yellowcard.mhra.gov.uk. Report all significant ADRs to patient's own GP (with patient consent).

Advice to patient/carer	**Follow-up advice to be given to patient or carer** • Client must be advised to attend an appropriate local healthcare provider (GP/ Sexual Health Service) following treatment if next period is delayed by more than 7 days, absent or abnormal e.g. exceptionally heavy or light and not typical of woman's usual cycle, if they experience pelvic pain or are otherwise concerned • Recommend a pregnancy test is taken at 3 weeks (see oral/ written information to be given to patient or carer) • Recommend referral / attendance at appropriate local healthcare provider (GP/ Sexual Health Service) for ongoing contraception and STI testing as required • If vomiting occurs within 3 hours of taking the tablet, client should return to pharmacy for replacement supply or seek medical assistance. • Advise client to read Manufacturer's Patient Information Leaflet • Please supply and advise client to read Patient Information Sheet (Appendix 1)

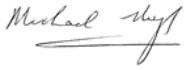
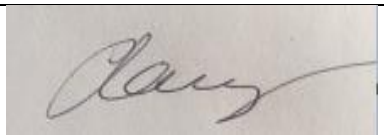
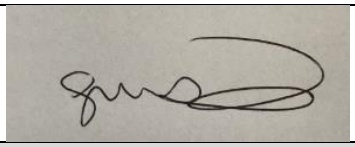
Arrangements for medicine supply	The Ulipristal acetate (UPA) 30mg should be dispensed from the community pharmacy stock labelled and recorded on the Patient Medical Record system. The client should be given a Patient Information Sheet (see Appendix 1) as well as the Manufacturer's Patient Information Leaflet for the UPA-EC. *The client should be encouraged to take the dose whilst in the pharmacy.*
Storage requirements	The usual community pharmacy storage of medicines requirements apply.
Follow up	Encourage client to put arrangements in place for further contraceptive advice and sexually transmitted infection (STI) prevention if needed. Apart from putting in place arrangements for future contraceptive advice and advice on STI, there is generally no need for routine follow-up post EC supply but advise to see GP or Integrated Sexual Health Service or have a pregnancy test if normal period is delayed by 7 days after its expected date. Advise of need to use appropriate barrier contraception for rest of present cycle if any possibility of further exposure to risk of pregnancy. Client to seek medical advice if risk of STI has occurred. Self-sampling STI test kits are available online via https://www.sh24.org.uk/orders/new If patient reports assault or rape, refer as appropriate (see Appendix 5 for contact details). If client wishes to use IUCD for EC, give Ulipristal acetate (UPA) 30mg (as long as meets criteria of this PGD) but refer to GP or Integrated Sexual Health Service for consideration of IUD insertion.

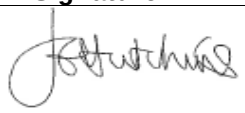
Referrals	**<u>Medical:</u>** An appropriate prescriber e.g. GP or Sexual Health Service should be referred to in the following situations: • If client wishes to use IUCD for EC Clients should be advised to seek medical attention promptly: • If any lower abdominal pain occurs in the 3-4 weeks after using emergency contraception because this could signify an ectopic pregnancy • If, in 3 to 4 weeks, the subsequent menstrual bleed is abnormally light, heavy or brief, or is absent, or if the client is otherwise concerned • If there is any doubt as to whether menstruation has occurred, a pregnancy test should be performed at least 3 weeks after UPSI **<u>Safeguarding:</u>** If under 16 years old, consider need to follow child protection process, including awareness of Child Sexual Exploitation. Please note that it is a mandatory requirement to refer those under the age of 13 years who present having had sexual intercourse. If client discloses allegation of rape, please refer as appropriate. **Please see Appendix 5 for safeguarding referral contact details.**

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

Leicester City Council, Leicestershire County Council and Rutland County Council will hold the original signed copy.

The PGD must be easily accessible in the clinical setting

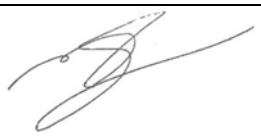
PATIENT GROUP DIRECTION WORKING GROUP		
NAME	**POSITION**	**SIGNATURE**
Dr. Mike McHugh	**Consultant in Public Health (Leicestershire and Rutland County Councils)**	
Luvjit Kandula	**Chair of Leicester, Leicestershire and Rutland Local Pharmacy Committee (up to end February 2019)**	
Sue Hind	**Interim Chief Officer Leicestershire and Rutland Local Pharmacy Committee**	

PATIENT GROUP DIRECTION CONTRIBUTORS		
Name	**Position**	**Signature**
Janet Hutchins	**Public Health Strategic Commissioner (Leicester and Rutland County Councils)**	
Ruth Adams	**Clinical Educator, Leicester Sexual Health (Midland Partnership NHS Foundation Trust)**	

This PGD is approved for use within the area covered by Leicestershire County Council and Rutland County Council.

PGD Authorisation and Adoption by Leicestershire and Rutland County Councils

Director of Public Health Leicestershire and Rutland County Councils	Name Mike Sandys

	Signature 
	Date 25.4.19

Responsibility for updating the PGD

Leicestershire County Council and Rutland County Council	Public Health commissioners will review the Service Specification to update the PGD.

References

1. www.medicine.org.uk
1. FSRH Guideline Emergency Contraception, 2017, https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/
2.
3. http://www.fsrh.org/pages/clinical_guidance.asp
4. http://pharmacyregulation.org/
5. https://www.cppe.ac.uk
6. Best practice guidance for doctors and other health professionals in providing advice and treatment to young people on contraception, sexual and reproductive health. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086960
7. http://www.fsrh.org/pdfs/SpottingTheSignsCSEproformaA4.pdf

Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

Pharmacy Details	
Name	
Address	
Telephone Number	

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.

Note to Authorising Managers:
Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.
Pharmacists should sign the table and keep their personal copy of this document.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

I also declare that I am aware that I have an obligation to keep my practice and knowledge up to date and to respond to any changes that affect the content of this PGD and any changes in the use of PGDs in general.

Name of Professional	Signature	GPhC No	Authorising Manager/ Superintendent (if appropriate)	Date

Appendix 1

Patient Information Leaflet:
Oral Emergency Contraception – Ulipristal/ellaOne

You have been supplied with Ulipristal/ellaOne emergency contraceptive pill.

You have been provided with a medicine containing Ulipristal. If you have any serious medical problems, or are taking, or have recently stopped taking any medicines, please make sure that you discuss these with the pharmacist, to ensure that this type of emergency contraception is safe for you.

Please let the pharmacist know of any medication you are taking, including over the counter medicines, herbal medicines or recreational drug use.

Please read this information and the information provided with your medication carefully and do not hesitate to speak to the pharmacist if you have any questions.

What does the emergency contraception pill do?

The emergency contraceptive pill when taken correctly reduces the chances that you will get pregnant after unprotected sex. But it is **not** 100% effective at preventing pregnancy after unprotected sex.
It does not prevent pregnancy if you have unprotected sex again after you have taken it.

You need to make sure you start using effective contraception immediately. The health practitioner will tell you when you can start the pill or have an implant after taking Ulipristal.

What is the emergency contraceptive IUD?

The copper intrauterine device (IUD) used for emergency contraception is the most effective method. It is more effective in preventing pregnancy after you have had unprotected sex than the emergency contraceptive pill. The copper IUD as emergency contraception needs to be inserted into the womb as soon as possible after unprotected sex. **It can be used even if you have been given the emergency contraceptive pill**. Once it has been inserted, it also works as an ongoing contraceptive method to prevent pregnancy. The copper IUD is one of the most effective contraceptive methods and it can stay in place for several years. You can have it taken out any time if you want to become pregnant.
If you would like to have a copper IUD for emergency contraception – **ACT NOW**.
The person giving you this leaflet will be able to advise you where to go to get more advice and have an emergency IUD fitted. You need to be aware that sometimes it may be too late to fit a copper IUD for emergency contraceptive purposes.

How to take the pill

You have been given one tablet of Ulipristal. Please take the medication now.

What to do if you feel sick

If you are sick (vomit) within three hours of taking the tablet, please contact the pharmacy you initially visited as soon as possible for a further supply. If the pharmacy you originally visited is not open, you may go to another pharmacy offering the service and explain the circumstances for a replacement supply.
Pharmacies offering the service are listed on www.leicestersexualhealth.nhs.uk
Contact would need to be made with the Pharmacy to find specific opening times.

If this is not possible, you should seek alternative medical advice (your GP practice or the Sexual Health Service) urgently. Contact 0300 124 0102, visit www.leicestersexualhealth.nhs.uk or call 111 for information of your nearest service.

If you vomit later than three hours, the Ulipristal will have already been absorbed into your system so you will not need a replacement dose.

What happens next

Your next period may be as normal or may be different to your usual cycle. It may:

- arrive earlier, on time or later than usual
- be lighter or heavier than normal
- you may have some irregular bleeding before your next period; this can range from spotting to being quite heavy

Do take a pregnancy test to make sure that you are not pregnant if you:

- feel pregnant or
- if you haven't had a normal period within three weeks of taking Ulipristal.

You may wish to buy a pregnancy test or free pregnancy testing is available at the Integrated Sexual Health Service and from a range of places supported by the service. Visit www.leicestersexualhealth.nhs.uk for further details.

If you have any sudden or unusual abdominal pain or irregular bleeding in the next few weeks, these could be signs of an ectopic pregnancy. Although this is not common, it is very serious, so you should seek urgent medical advice.

Ulipristal is very effective if taken as soon as possible after unprotected sexual intercourse but it will not prevent pregnancy in every case. If you do become pregnant despite taking Ulipristal, there is no evidence that it will harm the pregnancy.

Future Contraception

This dose of Ulipristal will not protect you against pregnancy if you have unprotected sexual intercourse in the future.

If you are not already taking a regular form of contraception please consider if this is appropriate for you and seek further advice from your own GP or visit the Sexual Health Service as soon as possible to avoid further risk of pregnancy.

If you are planning to start the pill or implant, it will be helpful to see your doctor or visit the Sexual Health Service soon as you may be offered a 'quick start' rather than waiting until your next period. Please tell them the name of the emergency contraception that you have taken to help them to advise if quick start is possible. (A photo of the box will be fine.)

Emergency contraception does not protect against sexually transmitted infections; however, condoms reduce the risk. Chlamydia is the most common sexually transmitted infection (STI) in 15-24 year olds and it often does not have any symptoms. Chlamydia can be detected by a simple test and is easily treated. Self-sampling STI test kits for chlamydia and other STIs are available online via: https://www.sh24.org.uk/orders/new Otherwise you can go to the Sexual Health Service clinic for STI testing.

Emergency contraception is not as effective as using other regular methods of contraception. For confidential information & advice about contraception,
please see your own GP or visit the Integrated Sexual Health Service.

Contact 0300 124 0102 or www.leicestersexualhealth.nhs.uk for more information and your nearest clinic.

Appendix 2

Client Assessment and Record Form for supply of ulipristal acetate (UPA) or levonorgestrel (LNG) for Emergency Contraception - to be used in conjunction with the approved PGDs ref XX and XXX
Consultation date: ……

Client Details			
Name	**Address (not mandatory)**	**Postcode**	**D. O. B.** **Age.**

Ethnicity (circle which applies)

White: British Irish Eastern European Other

Asian/Asian British: Indian Pakistani Bangladeshi Other

Black/Black British: African Caribbean Other

Mixed

Other

Not Stated

Confidentiality statement
This is a confidential service. **Whatever your age, you have a right to confidential advice.** **We will not give information to anyone (even if you are under 16) – including parents, other family members, care workers, school or your doctor, without your permission.** **The only reason that we may have to consider passing on confidential information without your permission, would be to protect you or someone else from serious harm. We will always try to discuss this with you first.** **Any information about you will be stored securely.**
Confidentiality discussed with client Y/N

Client History		
Details of current requirement for Emergency Contraception (tick all that apply)		
No contraception	Condom failure	Missed pill **(give LNG only)**
Vomited EC dose	Other – please state	

How long ago was UPSI (hours)?				
Self-reported Weight	Self-reported Height		BMI =	
Current regular method of contraception				
Condom	Pill (specify type)	IUD/S	None	Other (specify)
If missed Pills, give details **(give LNG only):**				
Menstrual cycle				
Day of cycle	Usual cycle length (days)	Regular Y/N	Has client had LNG or UPA since the LMP? Y/N If LNG then give repeat LNG only	

For supply of UPA , complete section A below.
For supply of LNG, complete section B below.

SECTION A: For UPA supply (PGD Ref PGDLR006)

Inclusion Criteria			
UPSI occurred within previous **120** hours? (Or within time judged to be clinically appropriate in relation to Cautions section of PGD) Y/N	Where a client has vomited the dose of UPA, was this within 3 hours of ingestion? Y/N	Have all options for Emergency Contraception been explained and the client prefers oral EC? Y/N	

Exclusion/Caution criteria (including follow up action)			
Criteria	**Y/N**	**Recommended follow up**	**Follow up taken (please detail)**
Clients aged 13 years or under		• Use of professional judgement to consider supply of oral EC, • There is a duty to seek further advice and onward referral to address child protection issues. **The Child Protection Team must be contacted for children aged 13 or under who present having had sexual intercourse.**	
Drug interactions		Refer to earlier guidance in PGD ref X	
Breastfeeding		FSRH recommends women can use UPA without restriction. Women to be advised not to breastfeed for a week / express and discard milk after UPA-EC	
Vomiting		If the request is due to an episode of vomiting which has occurred within 3 hours of taking the UPA dose, a replacement supply may be issued (see Appendix 3).	

Criteria	Y/N	Recommended follow up	Follow up taken (please detail)
Repeated use in same cycle		Advice client: • She may be pregnant (consider pregnancy test as appropriate) • Repeated use disturbs menstrual cycle • Consider IUD as preferred alternative • UPA will not interrupt a pregnancy (there is no epidemiological data to indicate that 30 micrograms UPA has an adverse effect on the foetus)	
Episodes of UPSI over 120 hours		Consider referral for IUD up to 120 hours from likely ovulation.	
Previous UPSI within the same cycle and treated with UPA		Consider providing UPA and referral for IUD.	
Previous UPSI within the same cycle and treated with LNG		If within 7 days of LNG do not supply and refer to LNG PGD. If LNG was taken >7 days ago UPA can be supplied. Consider referral for IUD.	
Severe hepatic dysfunction		Consider discussion with Integrated Sexual Health Service or GP. Pregnancy poses a significant risk in this group therefore expert opinion suggests use of UPA is acceptable.	
Possible pregnancy: • Vague menstrual history • Last menstrual period late/abnormal/different		• Consider pregnancy test. • UPA will not interrupt a pregnancy (there is no epidemiological data to indicate that 30 micrograms UPA has an adverse effect on the foetus)	
Clients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption		Consider discussion with Integrated Sexual Health Service or GP. Not listed as caution or contraindication in BNF	
Known acute porphyria		Consider discussion with Integrated Sexual Health Service or GP. Refer to Sexual Health Service or GP asap. Not listed as caution or contraindication in BNF	
Know hypersensitivity to UPA		Consider supply of LNG. Refer to GP or integrated sexual health service	
Client Over 25 years of age		Offer purchase of OTC supply. Refer to GP or sexual health services.	
Administering oral EC after ovulation		Advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. Advise IUCD would be more suitable and refer to GP or	

		sexual health service. Oral EC can still be issued in these circumstances in case this is an unusual cycle.	

SECTION B: For LNG supply, if UPA is excluded. (PGD Ref PGDLR007)

Inclusion Criteria

UPSI occurred within previous **96** hours? (Or within time judged to be clinically appropriate in relation to Cautions section of PGD)	Where a client has vomited the dose of oral EC, was this within 3 hours of ingestion?	Have all options for Emergency Contraception been explained and the client prefers oral EC?	Missed pills are in the timescales that cause loss of protection?
Y/N	Y/N	Y/N	Y/N

Exclusion/Caution criteria (including follow up action)

Criteria	Y/N	Recommended follow up	Follow up taken (please detail)
Clients aged 13 years or under		• Use professional judgment to consider supply of oral EC. • There is a duty to seek further advice and onward referral to address child protection issues. **The Child Protection Team must be contacted for children aged 13 or under who present having had sexual intercourse.**	
Clients currently taking enzyme inducing drugs or have stopped within the last 28 days		May be offered 3000 microgram dose of LNG (this is not based on evidence or within product license but on expert clinical judgement of balance of risks and benefits)	
Breastfeeding		FSRH recommends women can use progesterone-only emergency contraception without restriction.	
Client weighs 70kg or has a BMI of over 26		FRSH recommends women offered 3000 microgram dose of LNG	
Repeated use in same cycle		Advice client: • She may be pregnant (consider pregnancy test as appropriate) • Repeated use disturbs menstrual cycle • Consider IUD as preferred alternative • LNG EHC will not interrupt a pregnancy (there is no epidemiological data to indicate that 1500 micrograms LNG has an adverse effect on the foetus)	
Vomiting		If the request is due to an episode of vomiting which has occurred within 3 hours of taking the dose, a replacement supply may be issued (see Appendix 3 of PGD Ref X).	
Episodes of UPSI over 96 hours and UPA exclusions apply		Consider referral for IUD up to 120 hours from likely ovulation. Consider pregnancy test.	
Previous UPSI within the same cycle and treated with UPA		Consider providing UPA and referral for IUD. LNG must not be issued	

		within 7 days of UPA	
Severe hepatic dysfunction		Consider discussion with Integrated Sexual Health Service or GP. Pregnancy poses a significant risk in this group therefore expert opinion suggests use of a single dose of LNG 1.5mg is acceptable.	
Known breast cancer		Consider discussion with Integrated Sexual Health Service or GP.	
Severe malabsorption syndromes i.e. Crohn's			
Possible pregnancy: • Vague menstrual history • Last menstrual period late/abnormal/different		Consider pregnancy test.	
Clients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption		Consider discussion with Integrated Sexual Health Service or GP.	
Client given birth in last 3 weeks		EHC not required.	
Known acute porphyria		Consider discussion with Integrated Sexual Health Service or GP. Refer to Sexual Health Service or GP asap.	
Know hypersensitivity to levonorgestrel		Provide UPA if criteria met within PGD Refer to GP or integrated sexual health service	
Client Over 25 years of age		Offer purchase of OTC supply. Refer to GP or Integrated sexual health services.	
Administering oral EC after ovulation		Advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. Advise IUCD would be more suitable and refer to GP or sexual health service. Oral EC can still be issued in these circumstances in case this is an unusual cycle.	

Patient Competence & Confidentiality (Fraser Guidelines apply)

If under 16 years old, client must be assessed to be competent using Fraser Guidelines (Appendix 4) and give verbal consent.

1. Criteria for Competence (for supply all answers must be 'yes')	Yes	No
Does the client understand the advice that she has been given?		
Has the client been encouraged to discuss the situation with her parent/guardian?		
Is the client's physical and/or mental health likely to suffer unless she receives emergency contraceptive treatment?		
Is providing contraceptive advice and treatment in the client's best interest?		

If the answer to any of the above is no then the client must be referred to her GP or the local Sexual Health Service as a matter of priority so that treatment may still take place within the necessary timeframe.

2. Have any safeguarding, including child sexual exploitation, concerns been identified? (Referral information is in Appendix 5)
Suggested areas to consider: • age difference between couple and age of partner • where they met partner (internet/position of trust/via peers) • how long they have been together? • appears frightened of partner • any learning disability • understanding of abuse/coercion/exploitation • existing social worker Has a safeguarding referral been made YES/NO
Detail here any additional information relevant to your decision to supply oral emergency contraception to this young person

Action taken	
Supply of ulipristal acetate Y/N	Dosage (please specify)
Supply of levonorgestel Y/N	
Batch Number	Expiry Date
Comments:	
If supply is not given, please detail reason & onward referral action taken.	
Patient consent given to share information with GP or Integrated Sexual Health Service (if required). Y/N	
Record made on PMR & dispensing label provided Y/N	

Advice/Follow up Check List (tick to confirm discussed/actioned)			
Effectiveness, including failure rate & advice re: abdominal pain ☐	inform re: side effects ☐	Action if vomit within 3 hours ☐	Next period may be early/late ☐
Return if further UPSI ☐	Pregnancy test in 3 weeks ☐	If oral EHC fails: not harmful to pregnancy ☐	Encourage contact GP Sexual Health clinic for regular contraception ☐
Medication taken on premises ☐	Manufacturer's patient information leaflet and Patient Information Sheet (Appendix 1) issued ☐	STIs discussed and ways to access a screen provided. (Sexual health service or online test kit) ☐	Condom/information pack/c-card info issued. c-card distribution if appropriate. ☐

Confirmation and Consent
The stated action was based on the information given to me by the client. The client has consented to use of levonorgestrel outside of product license. (If applicable) Name of Pharmacist……. Signature of Pharmacist…… GPhC number ……. Date…… PHARMACY STAMP

Robust systems must be in place to meet the legal requirements of the Data Protection Act 1998 and the safeguarding of personal data at all times.

Appendix 3

The Fraser Guidelines in practice

If a client is believed to be under the age of 16 the pharmacist should**:**

- Assess the maturity of the client in terms of understanding any advice given
- Encourage the client to involve her parents
- Consider the effect on the physical or mental health of the client if advice or treatment is withheld
- 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 meets the Fraser Guidelines a supply of levonorgestrel may not be provided. The pharmacist should recommend (and assist where necessary) the client to attend their GP or the Integrated Sexual Health Service.

Fraser Competence – Clients Under 16 Years

The Gillick 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 (often referred to as Gillick Competence) 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)

Sexual Offences Act (2003) was made for prevention of sexual offences, and the protection of children from harm due to sexual acts. (http://www.legislation.gov.uk/ukpga/2003/42/section/1)

- The aim of the law is to protect the safety and rights of young people and make it easier to prosecute people who pressure or force others into having sex.
- Forcing someone to have sex is a crime.
- In England and Wales, under the law on Sexual Offences, the legal age for young people to consent to have sex is 16.
- In England, Wales and Northern Ireland those under the age of 13 years are considered unable to legally consent to sexual activity.
- Although the age of consent remains at 16, but the law should not be used to prosecute mutually agreed teenage sexual activity between two young people of a similar age, unless it involves abuse or exploitation.
- Under the Sexual Offences Act young people still have the right to confidential advice on contraception, condoms, pregnancy and abortion, even if they are under 16.
- The assessment of a young person's capacity to make a decision about contraception or medical treatment is a matter of clinical judgement guided by professional practice and local/national policy and is a legal requirement.
- Assumptions should not be made about an individual's capacity to consent based on age alone or disability

(Reference: SERVICE STANDARDS ON OBTAINING VALID CONSENT IN SEXUAL HEALTH SERVICES September 2014 Published by the Clinical Standards Committee, FSRH, (http://www.fsrh.org/pdfs/ConsultationConsentServiceStandard.pdf)

Appendix 4

Referral Proforma

Patient Group Direction – Emergency Contraception Referral by Community Pharmacist

Dear Doctor,

The named client below is considered to be unsuitable for issue of oral emergency contraception under the Leicestershire County & Rutland County Council's Patient Group Direction for Emergency Contraception due to reasons provided below. Please provide the necessary advice regarding emergency contraception and/or on-going health care.

Clients name	
Date of Birth	
Date and time of consultation with Pharmacist	
Details of client history and reason for referral	
Date of first day of LMP and day of cycle	
Length of normal cycle	
Hours since UPSI	
Normal method of contraception	
Any safeguarding concerns identified? Any actions taken?	

Yours faithfully

Pharmacist name:

GPHC number:

Pharmacy address:

Telephone number:

Appendix 5

Contact details below are correct at time of production (February 2019)

LLR Sexual Health Service for appointments, advice, information for patients	0300 1240102	www.leicestersexualhealth.nhs.uk
LLR Sexual Health Service (Professional helpline)	0300 1240102 (option 4) 0800 318908 (option 4) Available: Monday- Friday (9am -7.30pm) Saturday (9am – 1.30pm)	
LLR Sexual Health Service Prevention & Promotion Team for C-Card Scheme, pregnancy testing, advice and information for young people	LLR Sexual Health Service 0300 1240102 0800 318908	www.leicestersexualhealth.nhs.uk
Juniper Lodge: Sexual Assault Referral Centre (SARC)	0116 2733330	www.juniperlodge.org.uk
Rape Crisis (Jasmine House)	0116 2558852	www.jasminehouse.org.uk
Leicester Constabulary Sexual Assault Unit (SIGNAL team/child abuse Investigation Unit)	Call 101 0116 222 2222	
Safeguarding **If you think a child or young person is being abused or harmed, act straight away.** **If you have concerns about a child or young person, help is available 24 hours a day, seven days a week.**	**Leicestershire County Council** **0116 305 0005** Please complete the electronic Agency Referral Form which is available at the following link: https://www.leicestershire.gov.uk/leisure-and-community/community-safety/report-abuse-or-neglect-of-a-child **Rutland County Council** **01572 758407** Referrals to social care about children must be made in writing or confirmed in writing (by fax) after telephone contact is made. Postal address: Rutland County Council, Childrens Duty & Assessments, Catmose, Oakham, Rutland, LE15 6HP	

	Police **Non emergencies, call 101** **In emergencies, always dial 999** **ChildLine** **0800 1111** **www.childline.org.uk** **NSPCC helpline** **0808 800 5000** **help@nspcc.org.uk** **The Leicestershire and Rutland Local safeguarding Children Board procedures are available from:** **www.lrsb.org.uk and www.lcitylscb.org**