

Patient Group Direction Version 5.0

Administration/Supply of Levonorgestrel 1500 microgram tablet by appropriately trained, named community pharmacists across the cluster of Devon County Council and Torbay Council.

Patient Group Direction Version 2.0

Administration/Supply of Ulipristal Acetate 30mg tablet by appropriately trained, named community pharmacists across Devon County Council and Torbay Council.

Date of Implementation: 1st October 2021

Expiry Date: July 2024

Authorised for use in Devon County Council by

Steve Brown, Director of Public Health, Public Health Devon, Devon County Council

Signed:



Dated: 24.09.21

Patient Group Direction version 5

Supply of Levonorgestrel 1500 microgram tablet by appropriately trained, named community pharmacists across Devon and Torbay
Authorised for use in Devon County Council and Torbay Council areas by:

Organisation	Devon County Council
Name and Title	Steve Brown - Director of Public Health
Signature:	
Organisation	Torbay Council
Name and Title	
Signature	

Pharmacy Authorisation (Lead Pharmacist for the location named below):

I have read and approved this PGD for use by appropriate named registered pharmacists employed at Pharmacy and certify that this pharmacy is registered to provide Levonorgestrel Emergency Hormonal Contraception under the local Public Health Service. I understand that I am responsible for ensuring that my staff have adequate training to ensure that Levonorgestrel Emergency Hormonal Contraception is supplied to patients in strict accordance with this PGD.

Signed:	Date:
Print name:	Role:
Pharmacy Address:	

The Community Pharmacists named below, based at _____ Pharmacy which has been accredited under the Public Health Service are authorised to administer/supply Levonorgestrel 1500 microgram tablet as specified under this Patient Group Direction.

In signing this document, I confirm the following:

- I have read and understood the above mentioned PGD
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD and able to evidence this
- I agree to administer/supply the above preparations in accordance with this PGD and any related local service specifications

NAME

TITLE

SIGNATURE

DATE

- **Complete additional pages as necessary**
- **Retain original signed pages with authorising manager**

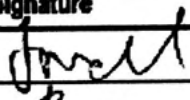
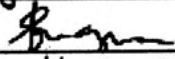
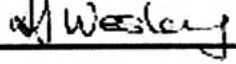
Patient Group Direction version 5.0

Supply of Levonorgestrel 1500 microgram tablet by appropriately trained, named community pharmacists across Devon and Torbay

Date of Introduction: August 2021

Review Date: July 2024

Developed by the Northern Devon Healthcare Trust Patient Group Direction Development Group and approved by the following members of the Group:

Developed By	Name	Signature	Date
Physician	Dr Jane Bush		22/6/21
Pharmacist	Ratidzai Magura		18-06-21
Practitioner	Alison Wesley		18-06-21

PGD developed in consultation with:

Organisation:	Northern Devon Healthcare NHS Trust
Name:	Dr Nikki Jeal
Title:	Consultant Reproductive Health and Contraception

SUPPLY OF LEVONORGESTREL 1500 MICROGRAM TABLET BY APPROPRIATELY TRAINED, NAMED COMMUNITY PHARMACISTS ACROSS DEVON AND TORBAY

1. Clinical Condition

Definition of condition/situation

- Levonorgestrel Emergency hormonal post-coital contraception (EHC) in individuals with a history of unprotected sexual intercourse (UPSI) or failed contraception according to agreed protocol.

Criteria for inclusion

- Person aged 13-24 years of age at risk of pregnancy, presenting within 96 hours of UPSI or failed contraception where there is a need for emergency contraception.
- A person who has received levonorgestrel EHC but has vomited within 3 hours of the dose (provided the repeat dose will be taken within 96 hours of unprotected sexual activity).
- A person requesting EHC should be counselled that insertion of a post-coital intra-uterine device (IUD) is the most effective form of emergency contraception and referral should be offered. If the patient chooses an IUD, provided the individual has presented within 96 hours of UPSI and there are no other contra-indications, levonorgestrel EHC can still be offered as a precaution (in case the individual misses their appointment)
- For any person aged less than 16 years, and aged 16 & 17 years, the pharmacist **MUST** undertake a competence assessment in accordance with the Fraser Guidelines. EHC can **ONLY** be provided under this PGD if the individual is assessed by the pharmacist as Gillick competent as per Fraser Guidelines. Records of this assessment must be kept in accordance with local service specifications and any agreed electronic reporting mechanisms. Discussion with the young person should explore the following issues:
 - 1) Whether the person is sufficiently mature to understand the advice given
 - 2) Advice and encouragement to discuss the situation with parents / guardian
 - 3) The effect on physical/ mental health if advice/treatment is withheld
 - 4) Whether supply of EHC is in the best interest of the individual

Criteria for exclusion

- Individuals aged 25 years and over
- Confirmed anaphylactic reaction to any previous dose or component of levonorgestrel 1500mg tablet.
- Any person aged less than 13 years - safeguarding issues must be addressed as per locally agreed safeguarding training and standards.
- Any individual under 16 years of age not considered to be Gillick Competent as per Fraser Guidelines- safeguarding issues must be addressed as per locally agreed safeguarding training and standards
- Presenting more than 96 hours after any UPSI. These patients should be referred to contraceptive services or their GP as it may still be appropriate to insert a post coital IUD.
- A person who has received Levonorgestrel EHC, but has vomited **MORE THAN 3** hours after the dose was taken, does not need to take a repeat dose. .
- Established pregnancy.
- Taking ciclosporin – increased risk of toxicity of ciclosporin
- Active acute porphyria
- Known, severe liver disease.
- A person with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Levonorgestrel 1500mg tablet contains lactose monohydrate.
- Representatives of individuals requesting levonorgestrel EHC – **supply to a third party is not permitted**
- Delivered a baby in the last 3 weeks
- Any situation where the pharmacist has clinical or professional reservations about supplying

Caution

- Patients taking any other medications - consult current BNF Appendix 1 for any potential interactions.
- Taking Liver Enzyme Inducing Drugs within the last 28 days - Always check individual drugs in current version of BNF. Examples include primidone, phenobarbital/phenobarbitone, phenytoin, carbamazepine, eslicarbazepine, oxcarbazepine, topiramate, rifampicin, rifabutin, griseofulvin, ritonavir and other drugs used to treat HIV - check individual drugs and seek specialist advice, herbal preparations containing St John's Wort. Follow dose adjustments in section 3. 'Dose to be used'
- If individual is taking drugs known to be teratogenic: advise individual to perform a pregnancy test 3 weeks after taking EHC. If the test is positive, the individual should contact their GP or the sexual health service.
- Safeguarding concerns must be considered for all ages including those under 16 years of age who are not considered to be Gillick competent as per Fraser Guidelines. Safeguarding issues must be addressed as per locally agreed safeguarding training and standards.
- Suspected pregnancy – levonorgestrel can still be given as there is no evidence that it is harmful in pregnancy
- Anticoagulants – the anticoagulant effect of warfarin and phenindione may be affected: ensure follow up occurs and INR is checked 3 days later.
- A person suffering from severe malabsorption syndromes, such as Crohn's Disease (EHC may not be effective. Advise individual to perform a pregnancy test 3 weeks after taking EHC. If the test is positive, the individual should contact their GP or the sexual health service.
- Breastfeeding – levonorgestrel EHC is not known to be harmful, but potential exposure can be reduced if the woman takes the tablets immediately after feeding
- Individuals who have already taken 1 dose of levonorgestrel EHC during the current menstrual cycle. Offer referral to GP/ Contraceptive Services for post-coital IUD. If IUD is not appropriate or the patient declines then it is permissible to treat with levonorgestrel EHC under this PGD (provided the person fulfils the inclusion criteria). However there is an increased risk of disruption to the menstrual cycle, this should be explained to the individual.
- Explain that EHC should not be relied upon as a regular form of contraception and that they should seek advice from their GP/ Contraceptive Services for a suitable form of contraception
- A person attending for multiple repeat doses of EHC: - Give EHC if there is no exclusion criterion AND refer to sexual health service for a reliable method start.

Action if excluded

- Refer to GP or contraception and sexual health service as appropriate. Any safeguarding issues must be addressed as per locally agreed safeguarding training and standards.

N.B. All consultations for supply of levonorgestrel EHC under this PGD should be recorded along with the action taken/ referrals made and advice given in accordance with local service specifications even if the patient is excluded from the PGD. All records should be retained securely and confidentially.

Action if patient refuses medication

- If the individual refuses the form of EHC offered, refer to GP or sexual health service. Refusal must be recorded in accordance with local service specifications requirements and any agreed electronic reporting mechanisms.

2. Characteristics of Staff

Qualifications required

Pharmacist registered with the General Pharmaceutical Council of Great Britain, commissioned by either Devon County Council or Torbay Council to provide Emergency Contraceptive Services as a Public Health Service.

Additional requirements

- Working within a named, accredited community pharmacy commissioned by either Devon County Council or Torbay Council to provide levonorgestrel EHC as a Public Health Service.
- The accredited Pharmacist must ensure their insurance policy includes professional indemnity cover for undertaking this service.
- Successful completion of the Centre for Pharmacy Practice (CPPE) package Emergency Hormonal Contraception and Safeguarding and Vulnerable Adults training as per the service specification.
- The pharmacist must have undertaken any additional training as defined within the local Devon and Torbay Public Health Service specification
- The Pharmacist must comply with any standards as defined within the local Devon and Torbay Public Health Service Specification

3. Description of Treatment**Name of Medicine**

Levonorgestrel 1500 micrograms tablet

Legal Class

POM (Prescription Only Medicine)

Storage

- Store below 25°C.

Dose to be used (including criteria for use of differing doses)

- **Presentation within 72hours:**
One tablet containing 1500micrograms levonorgestrel taken as soon as possible and not later than 72hours after unprotected intercourse or failed contraception.
- **Presentation between 72 hours and 96 hours:**
One tablet containing 1500micrograms levonorgesterol taken as soon as possible and not later than 96 hours after unprotected sexual intercourse or failed contraception with appropriate counselling regarding the unlicensed use, efficacy and follow up. **N.B This is an unlicensed use.**
If the individual is already taking the contraceptive pill- see protocol for advice
- **If taking liver enzyme inducing drugs (see cautions) or if BMI >26 or weight >70kg:**
The dose should be 2 tablets, each containing 1500micrograms levonorgestrel, taken as a single dose (total dose 3mg levonorgestrel), which should be taken as soon as possible and not later than 72hours (or 96 hours with appropriate counselling) after unprotected sexual intercourse or failed contraception. **N.B This is an unlicensed use.**

Method or route of administration

- Oral. The patient should be offered a glass of water and encouraged to take the dose at presentation, but this is not mandatory.

Total dose and number of times drug to be given. Details of supply (if supply made)

- Single dose, taken as soon as possible and not later than 72 hours or 96 hours in exceptional circumstance, after unprotected sexual intercourse or failed contraception, unless the person has vomited dose of levonorgestrel within the last three hours. See dosing schedule for patients also taking an enzyme –inducing drug/raised BMI.
- Should the patient wish to take the medication away with them, the patient should be issued with original manufacturers pack(s) each containing one tablet and a patient information leaflet.

Advice and information to patient/carer including follow-up

- Discuss the efficacy of the emergency contraception. Offer referral for IUD insertion to all individuals requesting EHC because it is the most effective form of contraception.
- Encourage the individual to take the tablet immediately, if administered on site, provide person with the manufacturer's Patient Information Leaflet.
- Explain to individual that they will not be protected from pregnancy for the rest of the cycle without additional contraception. Ensure that the individual knows where to obtain further contraceptive advice/ help.
- Advise the individual that levonorgestrel 1500mg can sometimes cause nausea but that vomiting is very unlikely to occur. However, if the individual does vomit within 3 hours of taking the medication they should return to the pharmacy or seek alternative medical advice as another dose will be required immediately (providing the repeat dose is still within 96 hours of unprotected intercourse).
- Explain to the individual, they may have some irregular bleeding between taking levonorgestrel 1500mg and the next period. This can range from spotting to quite heavy.
- Explain to the individual that they may experience disruption to the timing of their next period, but if the period is more than 7 days late the individual must have a pregnancy test because EHC is not 100% effective.
- Explain that the individual should seek medical advice if the next period is shorter or lighter than usual or the individual develops unusual/ sudden lower abdominal pain.
- Explain that the tablets are for emergency use only and not a regular method of contraception because it is not effective as regular contraception.
- Offer an opportunistic Chlamydia screening test and kit as part of the emergency contraception consultation. If it is not appropriate at the time, ensure that the person has details of how to access a test at another time.
- Advise on future contraception. Direct the individual to the Devon Sexual Health website www.devonsexualhealth.co.uk/ which includes details of local services.
- Use of emergency contraception does not replace the necessary precautions against sexually transmitted infections (STIs). Direct the individual to the Devon Sexual Health website www.devonsexualhealth.co.uk/ which includes details of local services.
- Ensure that any safeguarding issues are addressed as per locally agreed safeguarding training and standards.

Guidance on failed contraception and circumstances where emergency contraception is indicated should be obtained from:

Devon Sexual Health Professional Helpline – 01392 284960 Mon day to Friday 0900-1700 (excluding Bank holidays)

Specify method of recording supply /administration

- The pharmacist should record the consultation in accordance with local service specifications and any agreed electronic reporting mechanisms, including time and date of consultation. If levonorgestrel emergency contraception is supplied, then the pharmacist and individual should

Including audit trail

sign only when the pharmacist is confident that the person understands the information given.

- All records should be retained for 8 years (in adults) or until 25th birthday in a child (age 26 if the record is made when the young person was 17). All records must be retained securely to maintain confidentiality.

The following will be recorded in accordance with local service specifications and any agreed electronic reporting mechanisms:

- The date and time of supply
- The signature and name of the person supplying the medication.
- Whether the medication was witnessed as taken within the pharmacy.

Confidentiality:

All pharmacists and their supporting staff must respect their duty of confidentiality and information should not be disclosed to any third party without the individuals consent. This duty of confidentiality applies equally to patients who are less than 16 years of age **providing that safeguarding issues have been addressed**. Pharmacists should be aware of their obligations under their appropriate Code of Conduct/Ethics.

- The individual should be asked if they wish their GP to be informed. Supply may be communicated to the GP ONLY if consent is given first.

References used in the development of this PGD:

- National Institute for Health and Care Excellence, 2013, updated March 2017 NICE medicines practice guidelines [MPG2] Patient Group Directions | Guidance and guidelines | NICE
- British National formulary, BNF accessed online 05-05-2021
- Manufacturer's Summary of Product Characteristics : Levonelle One Step (Updated July 2020) online <https://www.medicines.org.uk/emc> [Accessed 05/05/2021]
- Faculty of Sexual & Reproductive Healthcare (FSRH) UK Medical Eligibility Criteria for contraceptive use(UKMEC, 2016, amended September 2019)
- Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit, Summary contraception after pregnancy (2017, amended October 2020) www.ffprhc.org.uk
- Faculty of Sexual & Reproductive Healthcare Clinical Guidance. Drug interactions with hormonal contraception, Clinical effectiveness Unit (January 2017, Reviewed 2019) and Appendices www.ffprhc.org.uk
- Faculty of Sexual & Reproductive Healthcare Clinical Guidance. Clinical Guideline on Emergency Contraception (January 2017, amended December 2020) and Appendices www.ffprhc.org.uk [Accessed 05/05/2021]
- Family Planning Association ; Your guide to the combined pill (2014, reprinted 2019) www.fpa.org.uk
- Family Planning Association ; Your guide to the progesterone only pill (2014, reprinted 2020) www.fpa.org.uk

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from the start of August 2021 and expires end of August 2024.

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.1	01/04/12	Old Patient Group Direction for the Supply of levonorgestrel (Levonelle® 1500) for Emergency Hormonal Contraception (EHC) by Appropriately Registered and Qualified Practitioners Employed in Primary Care- 10.1 version 2.0 obtained for review and amended to reflect current guidance	NHS Devon (Commissioning)
0.2	21/5/2012	Reviewed by Dr S Gobrial and amendments made re. referring women using Qlaira and Nuvaring to contraceptive services.	Medicines Management Team NHS Torbay.
1.0	26/6/2012	Amendments made based on comments from Virtual Review Panel	Medicines Management Team NHS Torbay.
1.1	25/9/2012	Error amended on page 6 in criteria for exclusion section- line stating that women who vomit within 2hrs of taking levonorgestrel EHC removed and replaced with a line stating that women who vomit MORE THAN 2hours after EHC need not take a repeat dose..	Medicines Management Team NHS Torbay.
1.2	01/05/14	Review of EHC PGD	Iain Carr
1.3	25/07/14	Amendments following PGD VRP	Iain Carr
2	15/8/2014	Final Formatting	Rachel Browse
3	13/4/2016	Review of PGD	Iain Carr
3.1	05/07/2018	Review of EHC PGD	Ratidzai Magura
	05/07/2018	Removal of requirement of patient/parent/guardian consent to be given in criteria for inclusion	Ratidzai Magura
	05/07/2018	Replaced the word person or individual where female, woman or client was previously used , to allow for gender neutral wording.	
	05/07/2018	Extension of inclusion criteria for levonorgestrel to be taken within 96hours where previous PGD stated 72hours.	
	05/07/2018	Removal of the statement child protection in the sentence 'child protection and safeguarding issues must be addressed as per	
	05/07/2018	Removal of the restriction on number of previous EHC doses received in current menstrual cycle to allow multiple issues .	
	05/07/2018	Removal of taking liver enzyme inducing drugs from exclusion criteria to caution section.	
	05/07/2018	Removal of patients with significant health problems such as hypertension, diabetes... from exclusion criteria.	
	05/07/2018	Removal of note for pharmacist to inform GP if patient on an anticoagulant is issues EHC.	
	05/07/2018	Removal of section on 'women who are taking the oral contraceptive pill ,contraceptive patch, or vaginal ring- as this is covered in protocol.	
	05/07/2018	Addition of the statements ' exclude pregnancy 3weeks post taking EHC if individual is taking any known teratogenic drugs'	

Version	Date	Brief Summary of Change	Owner's Name
	05/07/2018	Addition of the statement 'persons attending for multiple repeat doses of EHC, give as appropriate AND refer to sexual health service for reliable contraception.	
3.2	17/07/2018	Review and amendment to non-clinical information pertaining directly to the Devon County Council and Torbay Council Public Health Service for supply and administration of emergency contraception under a PGD	Julia Loveluck Senior Public Health Officer Sexual Health Devon County Council
3.3	30/08/2018	Correction of Devon County Council phone number Telephone: 01392 383000 (ask for public health)	Ratidzai Magura
	30/08/2018	Version history (3.2) date corrected to read 17/07/2018	Ratidzai Magura
	05/05/2021	Email address, Contact telephone numbers updated Website details for Devon Sexual Health updated	R.Magura

For more information on the status of this document, contact:	<u>For specific enquiries relating to clinical content:</u> Devon Sexual Health Services Tel contact: – 01392 284 960 This number is checked at regular intervals Monday to Friday 9:00 -1700 (excluding public holidays) <u>For all other enquiries Devon Council area:</u> Devon County Council Public Health 1st Floor Main Building County Hall Topsham Road Exeter EX2 4QD Email: Publichealth-mailbox@devon.gov.uk Telephone: 01392 383000 (ask for public health) <u>For all other enquiries Torbay Council area:</u> Torbay Council Public Health Directorate Torbay Council Town Hall Castle Circus Torquay TQ1 3DR Email: Publichealth@torbay.gov.uk Tel: 01803 207350
Date of Issue	
Reference	(Number Name version)
Path	H:SH&WD/prescribing/PGDs/Devon Wide PGDs/ Clinical Area / Number (Day Month Year)

Document Control

Title: Protocol for the provision of Emergency Hormonal Contraception by community pharmacists in the Devon County Council (DCC) and Torbay Council areas			
Author Dr Jane Bush Dr Nikki Jeal Dr Jane Simpson		Author's job title: Associate Specialist Doctor, Devon Sexual Health (NDHT) Doctor, Devon Sexual Health (NDHT) Doctor, Devon Sexual Health (TSDHCT)	
Directorate Specialist Services		Department Sexual Health	
Version	Date Issued	Status	Comment / Changes / Approval
1	July 2018	Original	Approved DTC - July 2018
2	August 2018		Substitution of 'roaccutane' with 'isotretinoin' –to reflect the fact that roaccutane is not the only brand of isotretinoin available (page 6).
			Removal of the line: 'If emergency contraception is supplied, then the pharmacist and individual should sign only when the pharmacist is confident that the person understands the information given' (page 7) (only electronic records are kept).
3	August 2018		Removal of the sentence 'concomitant use of drugs that increase gastric PH', from list of contraindications to UPA (page 10) Removal of the wording severe liver disease, breast cancer, or malabsorption syndromes- as examples of medical conditions (last paragraph on page 10).
4	April 2021		Updated contact names and email addresses Additional explanation of oral EC efficacy Valproate pregnancy prevention programme cited Additional comments advising referral for onward contraception
4	April 2021	Final	Addition of reference to Lapp lactase deficiency in 'History' medical history.
Approved at Devon Sexual Health Governance 21/04/2021			
Main Contact Drs J Bush and N Jeal Devon Sexual Health Northern Devon Healthcare Trust (NDHT) Raleigh Park Barnstaple, EX31 4JB		Tel: Direct Dial – 01392 284966/ 01271 341562 Email: jane.bush@nhs.net ; nikki.jeal1@nhs.net	
Lead Director Dr Fiona Fargie, Devon Sexual Health, Northern Devon Healthcare Trust			
Document Class Protocol		Target Audience Community pharmacists in the Devon County Council and Torbay Council areas	

Protocol for the provision of Emergency Hormonal Contraception by
community pharmacists in the Devon County Council (DCC) and Torbay Council areas

Distribution List Devon County Council Community Pharmacists: DCC Public Health Team Torbay Council Community Pharmacists: Torbay Public Health Team		Distribution Method Issued as part of a suite of documents to accredited community pharmacists contracted by DCC and Torbay public health teams, to provide Emergency Hormonal Contraception in community pharmacies: 1. Levonelle PGD 2. Ulipristal Acetate PGD 3. Protocol for the provision of Emergency Hormonal Contraception 4. Public Health Service specification for the provision of Emergency Hormonal Contraception	
Superseded Documents			
Issue Date: 2021		Review Date: October 2024	
		Review Cycle 3 years	
Consulted with the following stakeholders: Ratidzai Magura -Clinical pharmacist HIV & Sexual Health Devon Sexual Health (NDHT) Julia Loveluck – Senior Public Health Officer Sexual Health Devon County Council Sarah Aston – Public Health Specialist Torbay Council (review of doc 2021)		Contact responsible for implementation and monitoring compliance: Amanda Emmett Devon County Council Public Health	
		Education/ training will be provided by: Devon Sexual Health	
Approval and Review Process • Clinicians for Sexual Health Governance Group			
Local Archive Reference Local Path - Filename -			
Policy categories for Trust’s internal website (Bob)		Tags for Trust’s internal website (Bob) None	
Any revision to an NHSLA document requires the agreement of the Senior Governance Manager (Compliance)			

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1. Purpose

The purpose of this document is to detail the process for the management of and the provision of emergency contraception (EC) via PGD to a person aged 13- 24 years old who attends a community pharmacy requesting EC

2. Presenting/Complaint

The person requests EC following an episode of unprotected sex or concern that their contraceptive method may have failed.

3. History

The need for EC should be assessed as per flow chart- appendix A.

Exclude current pregnancy.

Exclude delivery of a baby within the last 21 days.

Ascertain:

The person's usual method of contraception. Avoid use of Ulipristal Acetate (UPA) if any use of progestogen (including contraceptive, HRT, Levonogestrel EC, Norethisterone) in last 7 days.

Pill errors can be complicated- avoid use of UPA, give Levonogestrel (LNG) and consider referral for PCIUD/specialist advice.

Previous use of EC this menstrual cycle. UPA should not be given if use of LNG in the preceding 7days and LNG should not be given within the 5 days following use of UPA. Repeat dosing can be given in a cycle as long as UPA is followed by UPA and LNG followed by LNG. Repeat dosing should alert pharmacist to the need for reliable contraceptive method and signposting or referral should be made to local sexual health services.

The person's medical history- specifically do they have severe asthma requiring use of oral corticosteroids currently, severe liver disease, severe renal disease, active acute porphyria, LAPP lactase deficiency? Seek specialist advice.

The person's medication usage:

UPA should not be used if current use or use in the last 28 days of any enzyme inducing medication and the dose of LNG should be doubled in this situation.

Enzyme inducing drugs – check BNF. Examples include, primidone, phenobarbital/phenobarbitone, phenytoin, carbamazepine, eslicarbazepine, oxcarbazepine, topiramate, rifampicin, rifabutin, Griseofulvin, ritonavir and other drugs used to treat HIV (seek specialist advice), modafinil, Aprepitant, Bosentan and herbal preparations containing St John's wort.

Ciclosporin – Note risk of toxicity with LNG.

Drugs that increase gastric PH may affect UPA.

Anticoagulants – warfarin and phenindione may be affected by LNG. Advise INR (international normalised ratio) to be checked 3 days after use LNG.

Allergy history: including previous adverse reactions to any of the ingredients in UPA/LNG

Is the person currently breast feeding? Breast feeding should not occur for 7 days following use of UPA.

4. **Assess safeguarding needs for all persons and Gillick competency as per Fraser guidelines for all persons <16 years of age and as per locally agreed safeguarding training and standards. Give EC as per PGD boundaries but refer to MASH/GP/Devon Sexual Health if there are any concerns.**
Examination

Assess the person's weight and BMI. The dose of LNG should be doubled if BMI >26 and/or weight >70kg. UPA is unaffected by weight.

An initial pregnancy test should be recommended to exclude current pregnancy if there has been repeated use of EC, menstrual irregularities, repeated pill errors. Refer onto GP or Devon Sexual Health for further advice.

5. **Treatment Pathway**

Advise all persons that the fitting of a copper intrauterine device (PCIUD or "coil") is the most effective method of EC. Signpost to Devon Sexual Health if the person is keen to consider a PCIUD BUT please give oral EC anyway in case and IUD cannot be fitted or the person changes their mind.

Advise all persons that if they have already ovulated with in this cycle oral EC may not work. Give oral EC anyway but a PCIUD fitting may be preferable.

Advise that the use of a **reliable method of contraception** is more effective at preventing pregnancy than repeated use of EC. Hormonal methods of contraception can be started/restarted immediately after use of LNG and on the 6th day following UPA. Signpost to GP or sexual health services for provision of ongoing method of contraception. Direct to Devon Sexual Health website for further information (<http://devonsexualhealth.co.uk/>)

Advise **condom use** until a reliable method of contraception becomes effective.

Advise a **pregnancy test, 3 weeks after use of EC**- bleed patterns can be unreliable following EC or when using hormonal methods contraception and cannot be relied on to exclude pregnancy.

Advise repeat dose of EC if they vomit within 3 hours of taking EC. Ensure it is the same type of EC as explained above.

Offer an opportunistic Chlamydia screening test and kit as part of the emergency contraception consultation. If it is not appropriate at the time, ensure that the person has details of how to access a test at another time, direct the individual to Devon Sexual Health website (<https://www.devonsexualhealth.nhs.uk>) which includes details of local services.

Use of emergency contraception does not replace the necessary precautions against sexually transmitted infections (STIs). Direct the individual to the Devon Sexual Health website (<https://www.devonsexualhealth.nhs.uk>) which includes details of local services.

Supply EC as per pathway and Patient Group Direction.

Guidance on failed contraception and circumstances where emergency contraception is indicated should be obtained from:

- The most recent version of the BNF;
- Other sources where necessary e.g. the Faculty of Sexual and Reproductive Healthcare guidance and the individual product Summary of Product Characteristics;
- Devon Sexual Health Professional Helpline – 01392 284960 or 01392 284931

The pharmacist is required to keep up to date with the latest guidance regarding appropriate indications for emergency contraception.

6. Discharge Pathway

The pharmacist is required to keep up to date with the latest guidance regarding appropriate indications for emergency contraception.

Signpost all persons to Devon Sexual Health or GP for on-going contraceptive provision.

Persons attending for multiple repeat doses of EC please provide EC on each occasion but refer to Devon Sexual Health services.

Teratogenic drugs. If use of teratogenic drugs (check BNF but common drugs are valproate and isotretinoin) the person must be made aware that pregnancy must be avoided and exclusion of pregnancy with a pregnancy test at 3 weeks following use of EC is paramount. Please refer to Devon Sexual Health or GP for a reliable contraceptive method.

Further actions for pharmacists dispensing valproate drugs are detailed in the national valproate pregnancy prevention programme:

Ref: <https://www.fsrh.org/news/mhra-update-valproate-pregnancy-prevention-programme-jan-2020/>

Complete the PharmOutcomes documentation and electronic record of consultation

The pharmacist should record the consultation in accordance with local service specifications and any agreed electronic reporting mechanisms, including time and date of consultation.

All records should be retained for 8 years (in adults) or until 25th birthday in a child (age 26 if the record is made when the young person was 17). All records must be retained securely to maintain confidentiality.

The following will be recorded in accordance with local service specifications and any agreed electronic reporting mechanisms:

- Batch number and expiry dates
- The date and time of supply/administration
- The name of the person administering/supplying the medication.
- Whether the medication was witnessed as taken within the pharmacy.

Confidentiality:

All pharmacists and their supporting staff must respect their duty of confidentiality and information should not be disclosed to any third party without the individuals consent. This duty of confidentiality applies equally to patients who are less than 16 years of age **providing that safeguarding issues have been addressed**. Pharmacists should be aware of their obligations under their appropriate Code of Conduct/Ethics.

7. Documents Consulted to Prepare This Protocol

Faculty of Sexual and Reproductive Healthcare CEU Clinical Guidance on Emergency Contraception. March 2017 (amended December 2020)

Faculty of Sexual and Reproductive Healthcare UKMEC 2016

**Faculty of Sexual and Reproductive Healthcare CEU Guidance on Drug interactions
with hormonal contraception. January 2017 (reviewed 2019).**

**Faculty of Sexual and Reproductive Healthcare CEU Clinical Guidance, Contraception
after Pregnancy. 2017 (amended October 2020).**

**Fraser Guidelines/Gillick Competency (Gillick v West Norfolk and Wisbech Area
Health Authority 1985 All ER 402-437)**

Health Authority 1985 All ER 402-437)

Safeguarding Children Devon County Council:
<https://www.devonchildrenandfamiliespartnership.org.uk/>

Safeguarding Children Torbay Council:
<http://www.torbaysafeguarding.org.uk/>

Safeguarding Adults Devon County Council:
<https://new.devon.gov.uk/devonsafeguardingadultsboard/>

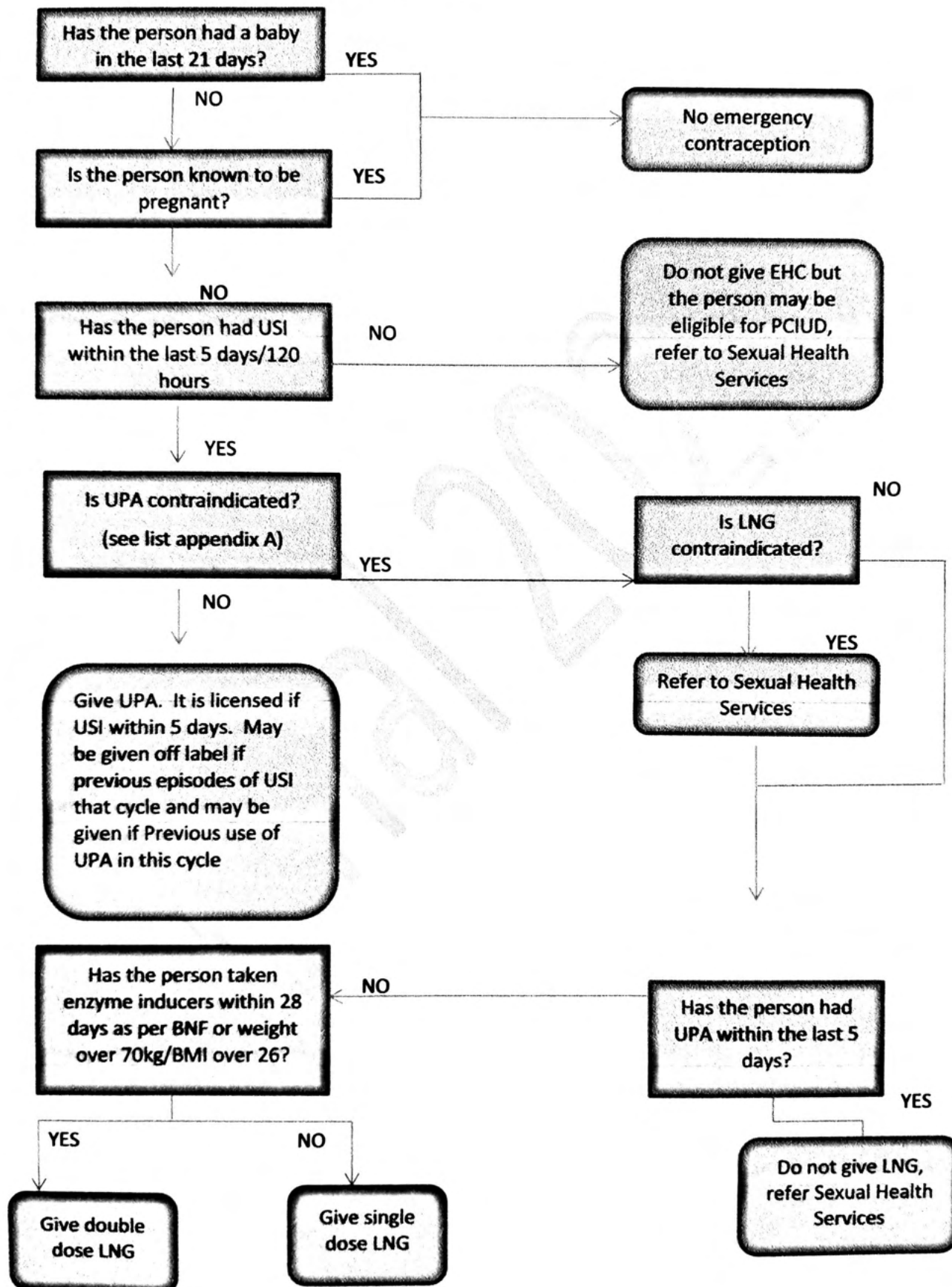
Safeguarding Adults Torbay Council:
<https://www.torbayandsouthdevon.nhs.uk/services/safeguarding-adults/>

Domestic Violence and Sexual Abuse Devon County Council:
<https://new.devon.gov.uk/dsva/>

Domestic and Sexual Violence Torbay Council:
<http://www.areyouok.co.uk/directory/torbay-domestic-abuse-service/>

Appendix A

Is emergency contraception required?



ADVICE ON GIVING UPA

1. If the person vomits within 3 hours they need a further dose of UPA
2. Delay restarting hormonal contraception or any other progestogens (HRT/Norethisterone/LNG) for at least 5 days. Use condoms until chosen method becomes effective
3. Suggest a pregnancy test in 3 weeks
4. Advise STI screen or chlamydia screen in 2-3 weeks
5. Consider safeguarding issues for all under 18-year olds and Fraser competency for 13-16-year olds
6. Advise overall pregnancy rate after use of UPA is approximately 1-2% BUT this is dependent on the timing of UPSI in relation to ovulation and once ovulation has occurred UPA will be ineffective.
7. Advise the person that PCIUD is the best method of emergency contraception and give them the contact details of Sexual Health Services

ADVICE ON GIVING LNG

1. If the person vomits within 3 hours they need a further dose of LNG
2. The person may immediately start or resume taking hormonal contraception with extra precautions until the chosen method becomes effective
3. Suggest a pregnancy test in 3 weeks
4. Advise STI screen or chlamydia screen in 2-3 weeks
5. Consider safeguarding issues for all under 18-year olds and Fraser competency for 13-16-year olds
6. LNG is thought to be approximately 85% effective if given within 72hrs of a single dose of UPSI but this is dependent on the timing of UPSI in relation to ovulation and once ovulation has occurred LNG will be ineffective.
7. Advise the person that PCIUD is the best method of emergency contraception and give them the contact details of Sexual Health Services

CONTRAINDICATIONS TO UPA (1)

1. Use of any progestogen in the previous 7 days (including all hormonal contraception, HRT, Norethisterone and Levonorgestrel (EHC)
2. Enzyme inducers in past 28 days as per BNF
3. Severe asthma requiring oral glucocorticoids
4. Breast feeding
5. Severe liver or kidney disease

If you have any concerns about suitability for any emergency contraception, e.g. in certain medical conditions or concomitant use of any drugs, refer to PGD initially and (or) contact Devon Sexual Health Services for advice.

Final 2021

Appendix B

Training and Accreditation Standards for Community Pharmacists in the Devon and Torbay area (excluding Plymouth)

Community pharmacists in the Devon County Council and Torbay Council area who wish to become accredited to deliver emergency hormonal contraception to people aged 13-24 yrs., must be registered with the General Pharmaceutical Council (GPhC) and meet the following standards as a minimum:

- Completion of the online CPPE **emergency contraception learning and assessment module** (revised 2018 - the reference number of these modules changes annually).
- Completion of the online CPPE **Level 2 safeguarding children and vulnerable adults learning and assessment** modules (revised 2018 - the reference number of these modules changes annually).
- Attend a locally approved training event organised by Devon Sexual Health
- Evidence of a DBS check as per organisational requirements¹

The CPPE sexual health in pharmacies self-learning package is currently recommended but not compulsory.

Locally approved training event delivered by Devon Sexual Health:

This session will include the following:

- The protocol for the provision of Emergency Hormonal Contraception by community pharmacists in the Devon and Torbay areas.
- How to make the best of the conversation with a young person
- Consent issues and assessing Fraser competence in young people and vulnerable young adults; being alert for areas of safeguarding concern and appropriate referral
- Promotion of sexual health in the pharmacy environment
- Chlamydia screening and the role of the pharmacist and proactively offering an opportunistic Chlamydia Screening Kit
- The role of Devon Sexual Health in managing positive results
- Recording and inputting information to PharmOutcomes (paperless record keeping).

¹ The Devon and Torbay contract for the provision of pharmacy based public health services states that: *the Applicant, as employers, confirm that they will ensure that all pharmacists and supporting staff are fit for the purposes for which they are employed i.e. suitably qualified and appropriately trained and vetted for the roles that they are undertaking (for example DBS checks as per organisational requirement). For more information see <https://www.gov.uk/government/organisations/disclosure-and-barring-service>.*

Counter Top Chlamydia Screening Kits for young people aged 16-24:

In a small number of cases pharmacists may only wish to provide counter top kits only for remote pick up by young people aged 16-24. The pharmacist will be expected to attend the locally approved training event delivered by Devon Sexual Health.

Refresher and Update Training:

Pharmacists are responsible for identifying their own learning needs and recording their Continuing Professional Development (CPD) in accordance with current GPhC standards. To remain accredited to provide Emergency Hormonal Contraception in the Devon and Torbay areas pharmacists are required to:

- Update specified CPPE learning and assessment modules in accordance with personal learning requirements
- Attend a 3-yearly refresher of the locally approved training delivered by Devon Sexual Health.

USEFUL INFORMATION

For details of the Devon and Torbay *locally approved training event* and *how to obtain a supply of Chlamydia Screening Kits*, contact the Devon Sexual Health Chlamydia Screening Administrator on 01392 284965 or by email at ndht.CSO@nhs.net.

List of local pharmacies in Devon and Torbay providing emergency contraception:

<http://devonsexualhealth.co.uk/images/pharmacies-providing-emergency-contraception.pdf>

List of local contraception and sexual health clinics in Devon and Torbay:

<http://devonsexualhealth.co.uk/clinics>

Devon Sexual Health Professional Helpline:

01392 284960 or

01392 284931