PATIENT GROUP DIRECTION (PGD)

For the supply of levonorgestrel

Version:	7
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SOMERSET

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FOR: The supply of levonorgestrel

VERSION CONTROL

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Version:	7

Document Change History

Version	Date	Comments
1	06/03/2018	Catherine Falconer first draft
2	19/03/2018	Michelle Hawkes amendments
3	15/03/2018	Amendments to include decision making algorithm
4	31/05/2018	Michelle Hawkes amendments
5	26/02/2021	Review and update by Michelle Hawkes
6	21/11/2022	Review and update by Michelle Hawkes. Reviewed against new national PGD template.
7	04/01/2023	Anne Cole (LPC) amendments

Author	Catherine Falconer
Document reference	

Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations' PGD governance system. The organisation's governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

PATIENT GROUP DIRECTION (PGD) FOR

Drug: Levonorgestrel 1.5mg tablet
Condition: Adults and children aged 12 years and older requiring progestogen-only emergency hormonal contraception within 72 hours of unprotected sexual intercourse (UPSI), and in exceptional circumstances between 73 hours and 96 hours of UPSI
Professional group: Registered Pharmacists
Professional Group:

You must be authorised by name, under the current version of this PGD before you attempt to work according to it

Clinical Condition		
1.	**Define condition / indication**	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly. Individuals aged 12 to 24 years requiring progestogen-only emergency hormonal post-coital contraception (EHC) within 72 hours of unprotected sexual intercourse (UPSI) or failed contraception. It may also be used between 72 hours and 96 hours (unlicensed use) although efficacy decreases with time.
2.	**Inclusion criteria**	Individuals including children aged 12 years and over where: • No contraceptive method was used, *or* • A contraceptive method is known to have failed, or • A contraceptive method is suspected of failure, or • A 'pill error' has occurred where emergency contraception is indicated (Refer to Faculty of Family Planning and Reproductive Health Care (FFPRHC) guidance) • For choice of emergency contraceptive method please refer to the decision-making algorithm in appendix 1. **And** *all* the following criteria are met: • No contraindications to the medication; • Valid consent from patient or person with parental responsibility has been obtained; • If under the age of 16 years, meeting the criteria of the 'Fraser ruling' regarding consent to treatment ('Fraser competence'). Discussion with the young person should explore the following issues: • Whether the individual is sufficiently mature to understand the advice given; • Advice and encouragement to discuss the situation with parents/guardian;

		• The effect on physical/mental health if advice/treatment is withheld; • Whether supply of EHC is in the best interest of the individual; • A discussion has occurred with the individual regarding alternative emergency contraception methods - ulipristral or copper intrauterine device (Cu-IUD) - to allow the individual to make an informed choice, and a referral is offered. o This should include that insertion of a Cu-IUD is the most effective form of emergency contraception, can be fitted for free up to 120 hours after UPSI, and provides the additional benefit of on-going contraception. If the patient chooses a Cu-IUD, provided the individual has presented within 72 hours of UPSI and there are no other contraindications, levonorgestrel can still be offered as a precaution (in case the patient misses the appointment) • Levonorgestrel is the most appropriate treatment; • 21 days or more have elapsed since giving birth
3.	**Exclusion criteria**	• **Aged 25 years or over** (at the discretion of the pharmacist there may be rare exceptions to this based on concerns about the ability of the patient to pay for over the counter EHC or seek help in time from another provider – see section 5). • **Informed consent not given.** • **Any UPSI more than 72 hours ago in this cycle** (or between 72 and 96 hours (unlicenced use) although efficacy decreases over time (see Emergency Contraception decision making flow chart or if appropriate consider providing ulipristal under PGD). N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 96 hours). • **Two previous administrations of levonorgestrel** within the current menstrual cycle. For patients who have already taken one dose of levonorgestrel during the current menstrual cycle a referral should be offered to GP / sexual health services for a Cu-IUD (see section 4 - previous EHC during current menstrual cycle below). • **Known pregnancy** (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI). • **Less than 21 days after childbirth.** • **Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).** • **Known hypersensitivity to the active ingredient or to any**

		component of the product – see Summary of Product Characteristics • **Vomiting more than 3 hours after** ingesting levonorgestrel - If the individual has received levonorgestrel but has vomited *more* than 3 hours after the dose was taken then they do not need to take a repeat dose • **UPSI within 12-hours of a previous dose of EHC** – The individual does not need a further dose of levonorgestrel • **Less than five days following ingestion of ulipristal emergency contraception** • **Severe liver disease / hepatic dysfunction** • **Porphyric individuals –** Individuals with active acute porphyria • **Bowel disorders** - Individuals suffering from bowel disease / disorders (e.g. Crohn's disease, ulcerative colitis etc.) causing malabsorption. Although the use of levonorgestrel emergency contraception (LNG-EC) is not contraindicated it may be less effective and so those individuals should be advised that insertion of a Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed • **Ciclosporin** – Individuals taking ciclosporin are at increased risk of ciclosporin toxicity • **Anaphylactic reactions** - Any individual who has had a true anaphylactic reaction to levonorgestrel, any other progestogen, or any component of levonorgestrel tablets, or having shown hypersensitivity after previous administration: see SPC for a full list of excipients • **Lactose-intolerant individuals** – Patients with rare problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorportion as levonorgestrel contains lactose monohydrate • **Breast cancer** – Individuals with either current or past breast cancer • **Not face-to-face** - The individual requesting EHC is not present in a face-to-face consultation (supply under this PGD is not allowed through telephone consultations apart from in exceptional circumstances, for example, the patient is unable to attend due to symptoms of COVID-19). • **Training -** Pharmacists who have not completed the Somerset County Council (SCC) approved training (see appendix 2) and do not have a current and completed Declaration of Competence for this service. • For individuals **16 years of age and over** and assessed as lacking capacity to consent.

		For individuals **under the age of 16 years**: • Not meeting the criteria of the 'Fraser ruling' regarding consent to treatment ('Fraser competence') if consent to treatment has not been obtained from a person with parental responsibility for the individual • Issues of child-protection have not been considered For individuals **age 12**: • Where a healthcare professional with expertise in child-protection issues has not been consulted. This should be prior to supply of EHC, although in exceptional circumstances if a child-protection expert is not available then supply can be made as long as they are contacted at the earliest opportunity, sufficient child protection issues are addressed, and a referral to child protection must be made. See associated child protection flow chart For individuals **under 12**: • Supply is not available under this PGD. A child protection expert must be contacted, and the patient must be managed according to child protection protocol • If the individual has not yet reached menarche (first menstrual cycle) consider onward referral for further assessment or investigation.
4.	**Cautions / Need for further advice**	• All individuals should be informed that insertion of a Cu-IUD within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. • Ulipristal emergency contraception (UPA-EC) can delay ovulation until closer to the time of ovulation than LNG-EC. Consider UPA-EC if the individual presents in the five days leading up to estimated day of ovulation. • **Other medications** - Consult current BNF for any potential interactions • **Known hypersensitivities** to any component of the levonorgestrel tablets, or any other progestogen, or having shown hypersensitivity after previous administration. See Summary of Product Characteristics

		• **Suspected pregnancy** – Levonorgestrel can still be given as there is no evidence that it is harmful but the patient should be advised to do a pregnancy test to exclude pregnancy • **Child protection -** Consider child protection issues including child sexual exploitation (CSE) risks in all individuals under 18 and the requirement to complete the Somerset CSE screening tool where risk is identified (consult with health professional with extensive experience in child protection); and the mandatory reporting requirement for disclosures of Female Genital Mutilation (FGM) for girls aged under 18 (call non-emergency '101' number by close of next working day) • **Safeguarding** – Consider safeguarding issues in all individuals age 18 and over (e.g. individuals with learning disabilities; domestic abuse) • **Previous EHC during current menstrual cycle** – For patients who have already taken one dose of levonorgestrel during the current menstrual cycle a referral should be offered to GP / sexual health services for a Cu-IUD. If a Cu-IUD is not appropriate, or the patient declines, then it is permissible to treat with levonorgestrel under this PGD (provided the patient fulfils the inclusion criteria) up to a maximum of twice during any one menstrual cycle. However, this is an unlicensed use of the drug and there is also an increased risk of disruption to the menstrual cycle. • **Liver enzyme inducing drugs** – Levonorgestrel metabolism is affected by liver enzyme-inducing drugs. Patients taking liver enzyme-inducing drugs, such as some antiepileptic drugs or patients receiving post-exposure HIV prophylaxis after sexual exposure (or who have stopped within the last 28 days) should be advised that a Cu-IUD is the only method of emergency contraception where efficacy is not reduced. If a Cu-IUD is not available or refused then two 1.5mg tablets levonorgestrel (3mg) should be administered and is permissible within this PGD as long as all other inclusion and exclusion criteria are satisfied. The Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guidance: Drug Interactions with Hormonal Contraception provides evidence-based recommendations and good practice points for health professionals on drug Interaction with Hormonal Contraception. The BNF and Stockley's Drug Interactions should also be consulted. • **St John's Wort** – May reduce the efficacy of levonorgestrel • **Breastfeeding** – Levonorgestrel is not known to be harmful, but potential exposure can be reduced if the individual takes the tables immediately after feeding

		• **Anticoagulants** – For patients with current venous thromboembolism it should be noted that the anticoagulant effect of warfarin and phenindione may be enhanced: the patient should be referred to their prescriber to ensure follow-up and INR is checked three-days after EHC • **Contraception** – It must be explained that emergency contraception should not be relied upon as a regular form of contraception and that they should seek advice from their GP / sexual health service for a suitable form of contraception, including the promotion of Long Acting Reversible Contraception (LARC) • **Sexually transmitted infection (STI)** – Explain that UPSI has potentially exposed the patient to an STI – Refer to GP or sexual health service for testing and treatment of STIs • **Aged 15 – 24** – Explain that UPSI has potentially exposed the patient to chlamydia. Discuss the need for chlamydia screening and offer a chlamydia screening kit, or refer to sexual health service or GP • **Prevention of STIs** – In addition to the promotion of LARC, pharmacists should highlight the importance of preventing sexually transmitted infections by promoting the use of condoms. For those aged 13-19 this should include promotion of the Somerset C-Card condom distribution scheme • **Missed oral contraceptive pill** – Consult FSRH (2017) guidance • **Guidance regarding different contraception** – Consult the current SPC for all different contraceptive products when dealing with requests for emergency contraception • **Body mass index (BMI)** – Consider ulipristal or double dose levonorgestrel if individual has a BMI ≥ 26kg/m^2 or weighs 70kg or more. Please note this dose differs from the product license. A Cu-IUD should be recommended as the most effective method of EC. If LNG-EC is to be given see dosage section. • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of LNG-EC is not contraindicated it may be less effective and so these individuals should be advised that insertion of a Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. • **Irregular vaginal bleeding –** The patient should be referred to their GP to explore underlying reasons • **Under 13 years of age** – A healthcare professional with extensive expertise in child-protection **MUST** be consulted before supply can be considered. In exceptional circumstances if a child-protection expert is not available then supply can be

		made as long as they are contacted at the earliest opportunity, sufficient child protection issues are addressed, and a referral to child protection must be made. See associated child protection flow chart • **NOTE**: A biological parent may not necessarily have parental responsibility for a child, therefore, may not be legally entitled to give consent for treatment. • If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
5.	**Action if excluded**	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate, for example the patient's GP, sexual health service and/or provide them with information about further options. • For individuals aged 25 and over years discuss/offer alternative emergency contraceptive method including over the counter purchase or referral to sexual health services or GP • If the individual is aged 25 years or over and there are any concerns about their ability to pay for over the counter EHC or seek help in time from another provider, EHC through the algorithm can be supplied with the pharmacist's discretion. • Any child protection, safeguarding and/or child sexual exploitation (CSE) issues must be addressed as per training.
6.	**Action if patient declines**	• If appropriate discuss with patient's GP or relevant specialist • Inform or refer to patient's GP or sexual health service as appropriate • Clearly document decision to decline treatment of the patient or person with parental responsibility
7.	**When further medical advice should be sought**	• Advice should be sought from a doctor or relevant specialist in the following circumstances: o If the patient is excluded from treatment o If the patient fulfils any of the criteria listed under the "Cautions" section that require further medical advice • If the patient is under 13 years of age advice MUST be sought from a healthcare professional with extensive expertise in child-protection issues prior to treatment under this PGD proceeding. In exceptional circumstances if a child-protection expert is not available then supply can be made as long as they are contacted at the earliest opportunity, sufficient child protection issues are addressed, and a referral to child protection must be made. See associated child protection flow chart

		If an adverse reaction does occur, provide immediate treatment and inform a doctor with responsibility for medical care of the individual as soon as possible. Report the reaction to CSM/MHRA using the "Yellow Card" system

PATIENT GROUP DIRECTION (PGD) F O R

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Condition: Adults and children aged 12 years and older requiring progestogen-only emergency hormonal contraception within 72 hours of unprotected sexual intercourse (UPSI), and in exceptional circumstances between 73 hours and 96 hours of UPSI
Professional group: Registered Pharmacists

8.	**Drug Details**	
	Name, form and strength of medicine	Levonorgestrel 1.5mg tablet
	Legal Category	Prescription Only Medicine (POM)
	Black Triangle Status	None
	Route / method of administration	Oral
	Dosage	One tablet (1.5mg) as a single dose treatment as soon as is practicable after unprotected sexual intercourse (UPSI)
	Off label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off-label use in the following conditions: ○ use between 72 and 96 hours post UPSI ○ consideration of increased dose for individuals with BMI ≥ 26kg/m^{2}or weight over 70kg ○ increased dose for individuals using liver enzyme inducing agents ○ severe hepatic impairment ○ individuals with previous salpingitis or ectopic pregnancy ○ lapp-lactase deficiency ○ hereditary problems of galactose intolerance ○ glucose-galactose malabsorption Note some products may be licensed only for certain age groups (e.g. 16 years and over) – supply of these products outside the licensed age groups is permitted under this PGD.

		Medicines should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence
	Frequency	Once as a single dose treatment, except: • If vomiting occurs within three hours of taking the levonorgestrel 1.5mg tablet a second supply of one levonorgestrel 1.5mg tablet may be made OR • For individuals taking medication that induces hepatic enzymes one dose of two levonorgestrel tablets (3mg) if a Cu-IUD is unavailable or refused • OR • For individuals with a BMI≥ 26kg/m^2 or body weight >70kg one dose of two levonorgestrel tablets (3mg) may be considered. AND • All inclusion and exclusion criteria still hold
	Duration of treatment	Single dose treatment
	Total dose number to supply / administer	One 1.5mg tablet *except:* • If vomiting occurs within three hours of the patient taking levonorgestrel 1.5mg tablet a repeat supply of a second single 1.5mg tablet is allowed, *or;* • For individuals taking medication that induces hepatic enzymes (see 'Cautions' section above) two levonorgestrel tablets (3mg) if Cu-IUD is unavailable or refused • Any individual with a BMI ≥ 26kg/m^2 or body weight over 70kg may be advised to take a total of 3mg (two 1.5mg tablets) as a single dose

		NOTE: All Prescription Only Medicines (POMs) must be labelled in accordance with the *Medicines Act 1968* for supply to a patient.
9.	**Identification & management of adverse reactions**	A detailed list of possible adverse reactions is available in the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following side effects are common with LNG-EC (but may not reflect all reported side effects): • Nausea and vomiting are the most common side effects. • Headache, dizziness, fatigue, low abdominal pain and breast tenderness, diarrhoea. • The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time
10.	**Reporting procedure of Adverse Reactions**	• Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's medical record. • All significant events / incidents / near misses occurring in relation to the supply of emergency hormonal contraception under this PGD must be reported to Somerset County Council on the relevant incident form in a timely manner
11.	**Written information and further advice to be provided**	• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If vomiting occurs within three hours of taking the dose, the individual should return for another dose. • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed.

		• Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur.
		• Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.
		• Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern.
		• Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs.
		• There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
		• Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased.
		• Useful contacts for patients include:
		  ○ Sexwise – www.sexwise.org.uk
		  ○ NHS Worth Talking About 0800 282930. Sexual health - NHS (www.nhs.uk)
		  ○ NHS Direct – 111
		  ○ Sexual health services in Somerset www.swishservices.co.uk
		  ○ Downloading the Somerset young people's sexual health app (Swish app)

12.	**Advice/follow up treatment**	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Individuals advised how to access on-going contraception and STI screening as required. • Further contact with other medical professionals, including safeguarding and child protection issues, as well as onward referrals should be managed as per requirements in exclusions/cautions/referral sections
13.	**Referral arrangements**	• **Late period / abnormal bleeding** - Patients should consult a GP, or a relevant specialist service if the

		patient's next period is seven or more days late or if abnormal bleeding occurs • **Sexually transmitted infections** (STI) - Refer patient to GP, or sexual health service for evaluation / treatment if the presence of sexual transmitted infection (STI) is known or suspected • **Chlamydia screening** – If between aged between 15 and 24 years offer chlamydia screening kit or refer to GP or sexual health service • **Anticoagulants** – The anticoagulant effect of warfarin and phenindione may be enhanced: the patient should be referred to their prescriber to ensure follow-up and INR is checked three-days after EHC • **Lower abdominal pain** - If any lower abdominal pain occurs, the patient should seek further medical evaluation (because the pain may signify an ectopic pregnancy) • **Contraception** – for emergency Cu-IUD fitting and / or ongoing contraceptive needs refer to general practice or SWISH • **Sexual health app** – Pharmacists should make use of the Somerset sexual health app (Swish app) to provide information to patients about other sexual health services available • **Aged over 25 years –** Advise on alternative arrangements for EHC including over the counter purchase or referral to GP or sexual health service
14.	**Record specific information for the supply/administration of medicines to include details for audit trail and significant events**	**Accredited pharmacists in Somerset are to use the PharmOutcomes system for recording purposes.** It is essential to record the following patient information: • Patient's name/address/date of birth and consent • Indications for use • Advice given to patient/carer to (include side effects) • Brand, batch number and expiry date of medicine • Name of medicine / dose/ quantity supplied Additionally the following is to be noted in the patient's record: • For individuals aged under 16: a statement as to the 'Fraser' competence of the individual • For children under 13 years of age: details of the discussion with the safeguarding expert prior to consideration of supply • For individuals with a BMI ≥ 26kg/m^2 or body weight >70kg, this is to be recorded

		• For individuals aged over 25 years and for whom levonorgestrel is supplied on the PGD using the discretionary clause, this is to be recorded. • **Records of all individuals receiving treatment with emergency hormonal contraceptives under this PGD need to be kept for clinical audit and medico-legal purposes. Therefore, the pharmacist working under this PGD must record supply of any medication through the PharmOutcomes system.** Records should be kept for at least eight years, or for children, until the child is 25 years old • Individuals supplied with medicines or have medicines administered under PGDs are subject to the normal NHS prescription charges and exemptions All emergency hormonal contraception should be stored in accordance with the specifications of this PGD and the SPC. • Document any adverse reactions • Where the child is not accompanied by a person with parental responsibility the name and relationship of the person bringing the child for treatment should be recorded **Serious events / incidents / near misses** - All significant events/incidents/near misses occurring in relation to the supply / administration of a medicine under this PGD must be reported on the relevant incident form in a timely manner
Staff Characteristics		
Professional qualifications		• Pharmacist registered with the General Pharmaceutical Council of Great Britain • Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation • Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions
Specialist competencies or qualifications		• The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical

	assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. • Pharmacists providing this service must have completed the Somerset County Council (SCC) approved training (see appendix 2) and have a current and completed Declaration of Competence for this service. • Pharmacist has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme • Suggested other training includes: successful completion of a relevant contraception module/course accredited or course endorsed by the FSRH, a university or as advised in the RCN training directory. Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions • Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
Continued education & training	• It is recommended that pharmacists access additional learning on Child Sexual Exploitation (e.g. NHS choices How to spot CSE) and Female Genital Mutilation (FGM_training_slides) • Individual continued Professional Development
Additional Requirements	• The health care professional is professionally accountable for this work and should be working within his / her competence • The manufacturers Summary of Product Characteristics (SmPC) (available at www.medicines.org.uk) must always be referred to for a more complete overview of the medicine supplied under this PGD • The pharmacist must be authorised by name under the current version of this PGD before working under it • The pharmacist must be able to access this PGD when needed

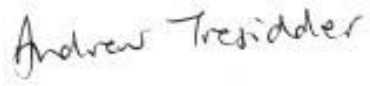
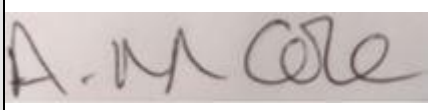
References used in this PGD

- Levonorgestrel National PGD template V2.0 March 2023 Supply and administration of levonorgestrel 1500 micrograms tablets for emergency contraception: PGD template last updated November 2022
- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 (Amended March 2000) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/
- FSRH CEU Statement Response to Edelman 2022 (August 2022) https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-response-to-edelman-2022-august-2022/
- Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
- Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines
- DH (2003) NHS code of practice https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200146/Confidentiality_-_NHS_Code_of_Practice.pdf
- DH (2004) Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health https://www.nice.org.uk/guidance/mpg2/resources/patient-group-directions-1779401941189
- DH (2006) Medicines Matters http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064325
- Levonelle 1500 Summary of Product Characteristics. https://www.medicines.org.uk/emc/medicine/16887

PATIENT GROUP DIRECTION (PGD) FOR:

Drug: Levonorgestrel 1.5mg tablet
Condition: Adults and children aged 12 years and older requiring progestogen-only emergency hormonal contraception within 72 hours of unprotected sexual intercourse (UPSI), and in exceptional circumstances between 73 hours and 96 hours of UPSI
Professional group: Registered Pharmacists

This patient group direction must be agreed to and signed by all health care professionals involved in its use. The Somerset County Council should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Organisation	

Authorisation	**Signature** **Date**
Nominated GP	 05/01/2023 Dr Andrew Tresidder MBBS Cert Med Ed GMC 2823735
Director of Public Health	 05/01/2023 Prof Trudi Grant, MSc PH, UKPHR, FFPH Director of Public Health Somerset County Council
Senior Pharmaceutical Advisor	 05/01/2023 Anne Cole, BPharm, MSc, FRPharmS
Consultant Microbiologist	N\A

(for Antibiotics)	

PATIENT GROUP DIRECTION (PGD) FOR

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Condition: Adults and children aged 12 years and older requiring progestogen-only emergency hormonal contraception within 72 hours of unprotected sexual intercourse (UPSI), and in exceptional circumstances between 73 hours and 96 hours of UPSI
Professional group: Registered Pharmacists

Individual Authorisation

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.

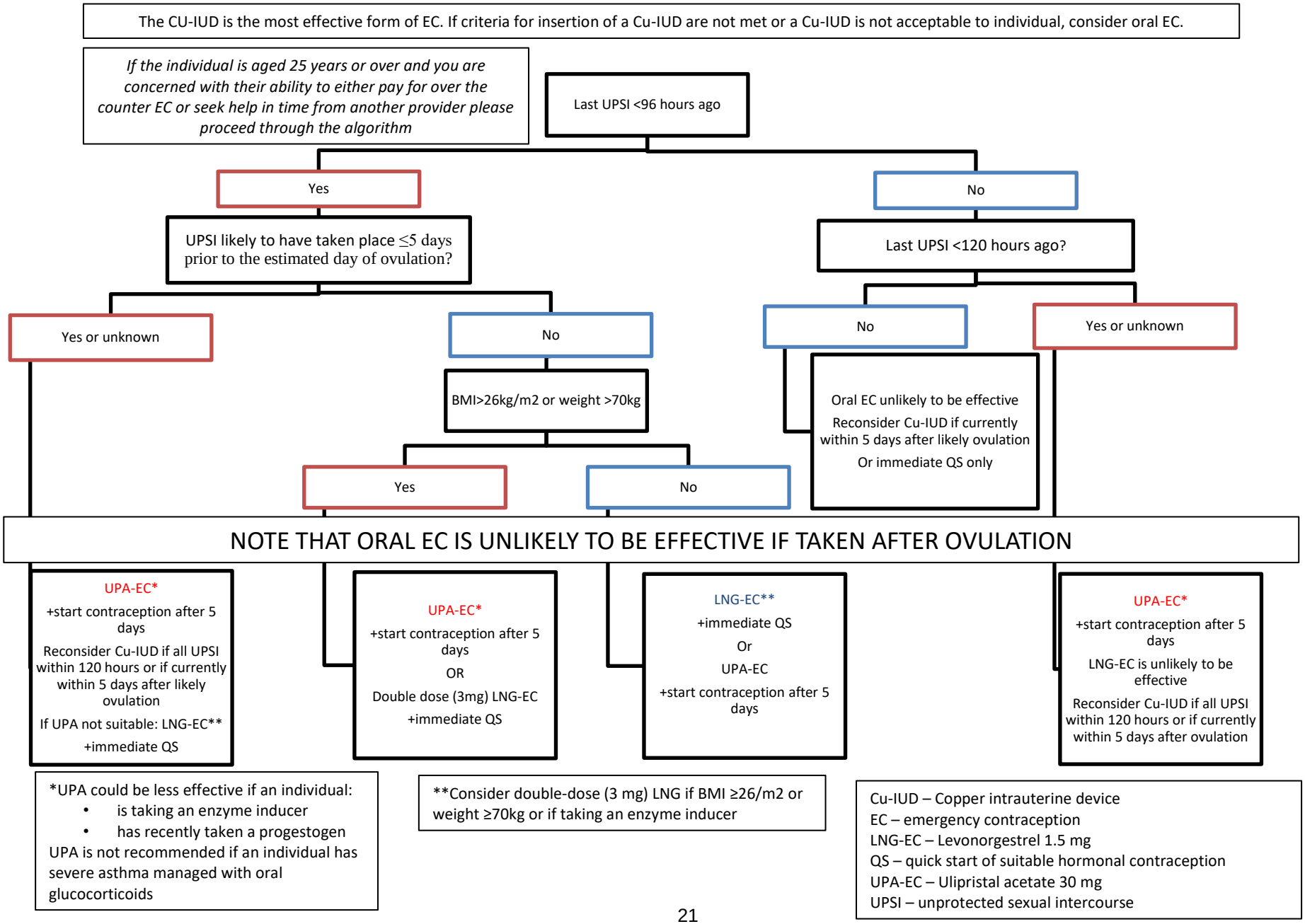
I have read and understood the Patient Group Direction and agree to supply / administer this medicine only in accordance with this PGD.

Location:				
Name of Professional	**Professional registration no. (pharmacists only**	**Signature**	**Authorising Manager[1]**	**Date**

Please ensure a copy of this page is kept by the Line Manager.

Pharmacist – please retain signed copy onsite and available for inspection by a Somerset County Council representative on request.

Appendix 1: Decision making algorithm for Oral Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) VS Ulipristal Acetate EC (UPA-EC)



Appendix 2: Mandatory and recommended training to be completed for the pharmacy Emergency contraception Patient Group Directions (PGDs) in Somerset

Format	Programme title	Repeat at least every:
Online workshops	**Somerset LPC and Somerset County Council Emergency contraception, safeguarding and child exploitation** (This is the preferred option - see the LPC bulletin and **website** for the next date and booking details) **Or** **CPPE Emergency contraception**	4 years (mandatory) **Or** 4 years (mandatory)
e-learning	**CPPE Emergency Contraception** **elearning for healthcare Safeguarding adults Level 2** **elearning for healthcare Safeguarding children Level 2** **CPPE Contraception** **elearning for healthcare Patient Group Directions** **CPPE Safeguarding children, young people and adults: level 2 case studies for pharmacy professionals** **CPPE Consultation skills: what good practice looks like**	2 years (mandatory) 2 years (mandatory) 2 years (mandatory) Once (recommended) Once (recommended) Once (recommended) Once (recommended)
e-assessment	**CPPE Emergency contraception** **CPPE Consultation skills for pharmacy practice** **CPPE Contraception**	2 years (mandatory) Once (recommended) Once (recommended)

Complete and sign the **CPPE Declaration of Competence for Emergency contraception** (recommended review at least every 2 years) and allow your data to be shared with PharmOutcomes in **MyCPPE:**