

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

### **PATIENT GROUP DIRECTION (PGD)**

**Administration of levonorgestrel 1500 micrograms tablet(s) for emergency contraception for the pharmacy contractor provision of an emergency hormonal contraceptive service in Somerset Community Pharmacies**

Version:	9
Name of Originator/Author:	Michelle Hawkes
Approved by:	Shelagh Meldrum, Chief Nursing Officer NHS Somerset ICB (Acting as Clinical Governance Lead)
Date issued:	1 <sup>st</sup> April 2025
Review date:	September 2027
Expiry date:	31 <sup>st</sup> March 2028

**Administration of levonorgestrel 1500 micrograms tablet(s) for emergency contraception for the pharmacy contractor provision of an emergency hormonal contraceptive service in Somerset Community Pharmacies**

<b>Document Status:</b>	Authorised
<b>Author</b>	Michelle Hawkes
<b>Name of originating author</b>	Cat Falconer
<b>Version:</b>	9

<b>Change History</b>	
<b>Version and date</b>	<b>Comments</b>
Version 8 17 <sup>th</sup> March 2025	First draft, using new national PGD template (April 2023) <a href="#">Implementing the National Patient Group Direction (PGD) Templates – SPS</a> <a href="#">Levonorgestrel-National-PGD-template-V2.0-Nov-24.doc</a>  Change in PGD to reflect extension of emergency hormonal contraception in community pharmacy service to those aged 25 and over.
Version 9	Safeguarding and formatting amendments.

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in October 2022.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

<b>Name</b>	<b>Designation</b>
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service

Name of PGD: Administration of LNG-EC emergency contraception v9.0  
Valid from: 1<sup>st</sup> April 2025  
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	(BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
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Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
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Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
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Alison Crompton	Community pharmacist
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Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

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

ORGANISATIONAL AUTHORISATIONS			
Name	Job title and organisation	Signature	Date
Senior doctor	Dr Andrew Tresidder NHS Somerset Medicines Programme Board Chair	<i>Andrew Tresidder</i>	1.4.2025
Senior pharmacist	Hels Bennett Medicines Manager NHS Somerset ICB	<i>H. M. Bennett</i>	27.03.2025
Person signing on behalf of authorising body	Shelagh Meldrum Chief Nursing Officer NHS Somerset ICB (Acting as Clinical Governance Lead)	<i>Shelagh Meldrum</i>	4.4.25

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

<b>1. Characteristics of staff</b>	
<b>Professional qualifications</b>	<ul style="list-style-type: none"> <li>• Pharmacist registered with the General Pharmaceutical Council of Great Britain</li> <li>• Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation</li> </ul>
<b>Specialist competencies or qualifications</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Pharmacists providing this service must have completed the Somerset Council (SC) approved training (see appendix 2) and have a current and completed Declaration of Competence for this service.</li> <li>• Pharmacist has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - <a href="#">eLfh PGD eLearning programme</a></li> <li>• Suggested other training includes: successful completion of a relevant contraception module/course accredited, or course endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory.</li> <li>• Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></li> <li>• 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.</li> <li>• The healthcare professional has completed training and is up to date with service requirements for</li> </ul>

	<p>safeguarding children and vulnerable adults (including domestic abuse).</p> <ul style="list-style-type: none"> <li>• Organisational PGD and/or medication training as required by employing Trust/organisation.</li> </ul>
<b>Continued education &amp; training</b>	<ul style="list-style-type: none"> <li>• It is recommended that pharmacists access additional learning on Child Sexual Exploitation (e.g. <a href="#">NHS choices How to spot CSE</a>) and Female Genital Mutilation (<a href="#">FGM training slides</a>).</li> <li>• Individual Continued Professional Development.</li> </ul>
<b>Additional Requirements</b>	<ul style="list-style-type: none"> <li>• The health care professional is professionally accountable for this work and should be working within his / her competence.</li> <li>• The manufacturers Summary of Product Characteristics (SmPC) (available at <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>) must always be referred to for a more complete overview of the medicine supplied under this PGD.</li> <li>• The pharmacist must be authorised by name under the current version of this PGD before working under it.</li> <li>• The pharmacist must be able to access this PGD when needed.</li> </ul>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

2. Clinical Condition	
Clinical condition or situation to which this PGD applies	<ul style="list-style-type: none"> <li>To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly.</li> </ul>
Inclusion criteria	<ul style="list-style-type: none"> <li>Individual presenting for emergency contraception (EC) between 0 and 96 hours following UPSI or when regular contraception has been compromised or used incorrectly.</li> </ul> <p>Individuals where:</p> <ul style="list-style-type: none"> <li>No contraceptive method was used, <i>or</i></li> <li>A contraceptive method is known to have failed, <i>or</i></li> <li>A contraceptive method is suspected of failure, <i>or</i></li> <li>A 'pill error' has occurred where emergency contraception is indicated (Refer to Faculty of Family Planning and Reproductive Health Care (FFPRHC) guidance)</li> <li>For choice of emergency contraceptive method please refer to the decision-making algorithm in Appendix 1.</li> </ul> <p><b>And all</b> the following criteria are met:</p> <ul style="list-style-type: none"> <li>No contraindications to the medication;</li> <li>Valid informed consent given;</li> <li><b>Individual is aged 12 years</b> or above (Note: If individual is 12 years old see additional safeguarding requirements in Cautions section and see also Appendix 3).</li> <li>If <b>under the age of 16 years</b>, meeting the criteria of the <a href="#">Fraser guidelines</a> regarding consent to treatment.</li> <li>A discussion has occurred with the individual regarding alternative emergency contraception methods - ulipristal or copper intrauterine device (Cu-IUD) - to allow the individual to make an informed choice, and a referral is offered. <ul style="list-style-type: none"> <li>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 96 hours of UPSI and there are no other contraindications, levonorgestrel can still be offered as a precaution (in case the patient misses the appointment)</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>• Levonorgestrel is the most appropriate treatment;</li> <li>• 21 days or more have elapsed since giving birth.</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Informed consent not given.</li> <li>• <b>Individuals under 12 years - supply is not available under this PGD.</b> A child protection expert <b>must</b> be contacted, and the patient must be managed according to child protection protocol (see Appendix 3).</li> <li>• <b>Individuals under 16 years</b> old and assessed as lacking capacity to consent using the <a href="#">Fraser guidelines</a>.</li> <li>• Individuals 16 years of age and over and assessed as lacking capacity to consent.</li> <li>• This episode of UPSI occurred more than 96 hours ago. 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. (see Emergency Contraception decision making flow chart or if appropriate consider providing ulipristal under PGD).</li> <li>• 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).</li> <li>• Less than 21 days after childbirth.</li> <li>• Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).</li> <li>• Known hypersensitivity to the active ingredient or to any component of the product – see <a href="#">Summary of Product Characteristics</a>.</li> <li>• Use of ulipristal acetate emergency contraception in the previous 5 days.</li> <li>• Acute porphyria.</li> <li>• Not face-to-face - The individual requesting EHC is not present in a face-to-face consultation (the EHC must be given through supervised administration).</li> </ul>
<b>Cautions including any relevant action to be taken</b>	<ul style="list-style-type: none"> <li>• All individuals should be informed that insertion of a copper intrauterine device (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 administer oral EC and refer to the appropriate health service provider.</li> </ul>

	<ul style="list-style-type: none"> <li>• Ulipristal emergency contraception (UPA-EC) can delay ovulation until closer to the time of ovulation than levonorgestrel (LNG-EC). Consider UPA-EC if the individual presents in the five days leading up to estimated day of ovulation.</li> <li>• LNG-EC is ineffective if taken after ovulation.</li> <li>• If individual vomits within three hours from ingestion, a repeat dose may be given.</li> <li>• Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them – see dose frequency section.</li> <li>• Body Mass Index (BMI) <math>&gt;26\text{kg/m}^2</math> or weight <math>&gt; 70\text{kg}</math> – individuals should be advised that although oral EC methods may be safely used, a high BMI may reduce effectiveness. A Cu-IUD should be recommended as the most effective method of EC. If LNG-EC is to be given see dosage section.</li> <li>• 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 contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed.</li> <li>• <b>If the individual is less than 16 years</b> of age an assessment based on Fraser guidelines must be made and documented.</li> <li>• <b>If the individual is less than 13 years</b> a healthcare professional with expertise in child protection <b>MUST</b> be consulted. See Appendix 3.</li> <li>• <b>If the individual is aged 12 years</b> – EHC can be administered, however a healthcare professional with expertise in child protection issues <b>must</b> be contacted. Administration of EHC should not be delayed. If a child protection expert is not available at the time of consultation then EHC can be administered as long as they are contacted at the earliest opportunity, sufficient child protection issues are addressed, and a referral to child protection is made. See safeguarding flowchart in Appendix 3).</li> <li>• <b>Child protection</b> - 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</li> </ul>
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	<p>(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)</p> <ul style="list-style-type: none"> <li>• <b>Safeguarding</b> – Consider safeguarding issues in all individuals age 18 and over (e.g. individuals with learning disabilities; domestic abuse)</li> <li>• <b>Contraception</b> – It must be explained that emergency contraception should not be relied upon as a regular form of contraception. Discuss offer of oral contraception if provided at the pharmacy or advise to seek advice from their GP / sexual health service for a suitable form of contraception, including the promotion of Long Acting Reversible Contraception (LARC)</li> <li>• <b>Sexually transmitted infection (STI)</b> – Explain that UPSI has potentially exposed the patient to an STI – Refer to GP or sexual health service for testing and treatment of STIs</li> <li>• <b>Aged 15 – 24</b> – 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</li> <li>• <b>Prevention of STIs</b> – 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</li> <li>• If the individual has not yet reached menarche consider onward referral for further assessment or investigation.</li> </ul>
<b>Action if excluded</b>	<ul style="list-style-type: none"> <li>• Explain the reasons for exclusion to the individual and document in the consultation record.</li> <li>• 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.</li> </ul>
<b>Action if patient declines</b>	<ul style="list-style-type: none"> <li>• If appropriate discuss with patient's GP or relevant specialist</li> <li>• Inform or refer to patient's GP or sexual health service as appropriate</li> </ul>

	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Clearly document decision to decline treatment.</li> </ul>
<b>When further medical advice should be sought</b>	<ul style="list-style-type: none"> <li>• Advice should be sought from a doctor or relevant specialist in the following circumstances: <ul style="list-style-type: none"> <li>○ If the patient is excluded from treatment</li> <li>○ If the patient fulfils any of the criteria listed under the "Cautions" section that require further medical advice</li> </ul> </li> <li>• <b>If the individual is less than 13 years</b> a healthcare professional with expertise in child protection <b>MUST</b> be consulted. See Appendix 3.</li> <li>• <b>If the individual is aged 12 years – EHC</b> can be administered, however a healthcare professional with expertise in child protection issues <b>must</b> be contacted. Administration of EHC should not be delayed. If a child protection expert is not available at the time of consultation then EHC can be administered as long as they are contacted at the earliest opportunity, sufficient child protection issues are addressed, and a referral to child protection is made. See safeguarding flowchart in Appendix 3).</li> </ul> <p>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</p>

3. Description of treatment	
<b>Name, strength and formulation of drug</b>	Levonorgestrel 1500 micrograms tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
<b>Legal Category</b>	Prescription Only Medicine (POM)
<b>Route / method of administration</b>	Oral
<b>Off label use</b>	<p>Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the <a href="#">Summary of Product Characteristics</a> (SPC).</p> <p>This PGD includes off-label use in the following conditions:</p> <ul style="list-style-type: none"> <li>○ use between 72 and 96 hours post UPSI</li> <li>○ consideration of increased dose for individuals with BMI <math>\geq 26\text{kg/m}^2</math> or weight over 70kg</li> <li>○ increased dose for individuals using liver enzyme inducing agents</li> <li>○ severe hepatic impairment</li> <li>○ individuals with previous salpingitis or ectopic pregnancy</li> <li>○ lapp-lactase deficiency</li> <li>○ hereditary problems of galactose intolerance</li> <li>○ glucose-galactose malabsorption</li> </ul> <p>Note some products may be licensed only for certain age groups (e.g. 16 years and over) – administration of the products outside the licensed age groups is permitted under this PGD.</p> <p>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.</p> <p>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</p>

<b>Dosage and frequency of administration</b>	<ul style="list-style-type: none"> <li>Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI.</li> <li><b>Dose for those individuals taking enzyme inducing medicines or herbal products:</b> An individual who requests LNG-EC whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. <b>Note</b> the effectiveness of this regimen is unknown.</li> <li><b>Dose for those individuals with a body mass index of more than 26kg/m<sup>2</sup> or who weigh more than 70kg:</b> An individual who requests LNG-EC with a body mass index of more than 26kg/m<sup>2</sup> or who weighs more than 70kg can be offered a total of 3mg LNG-EC (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. <b>Note</b> the effectiveness of this regimen is unknown.</li> </ul>
<b>Duration of treatment</b>	<ul style="list-style-type: none"> <li>A single dose is permitted under this PGD.</li> <li>If vomiting occurs within three hours of LNG_EC being taken a repeat dose can be supplied under this PGD.</li> <li>Repeated doses, as separate episodes of care, can be given within the same cycle. Please note: <ul style="list-style-type: none"> <li>If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC)</li> <li>If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC).</li> </ul> </li> <li>All inclusion and exclusion criteria still hold</li> </ul>
<b>Quantity to be supplied</b>	<ul style="list-style-type: none"> <li>Appropriately labelled pack of one tablet.</li> <li>Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m<sup>2</sup> or who weigh more than 70kg</li> </ul>
<b>Storage</b>	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
<b>Drug interactions</b>	<p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> or the BNF <a href="http://www.bnf.org">www.bnf.org</a></p> <p>Refer also to <a href="#">FSRH guidance on drug interactions with hormonal contraception</a></p>

<b>Identification &amp; management of adverse reactions</b>	<p>A detailed list of possible adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="http://www.bnf.org">www.bnf.org</a></p> <p>The following side effects are common with LNG-EC (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> <li>• Nausea and vomiting are the most common side effects.</li> <li>• Headache, dizziness, fatigue, low abdominal pain and breast tenderness, diarrhoea.</li> <li>• 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.</li> </ul>
<b>Management of and reporting procedure of adverse reactions</b>	<ul style="list-style-type: none"> <li>• 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: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the individual's medical record.</li> <li>• Report any adverse reactions via organisation incident policy.</li> </ul>
<b>Written information and further advice to be provided</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Ensure that a patient information leaflet (PIL) is provided within the original pack.</li> <li>• If vomiting occurs within three hours of taking the dose, the individual should return for another dose.</li> <li>• Explain that menstrual disturbances can occur after the use of emergency hormonal contraception.</li> <li>• Provide advice on ongoing contraceptive methods, including how these can be accessed.</li> <li>• 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.</li> <li>• 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.</li> <li>• Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more</li> </ul>

	<p>than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern.</p> <ul style="list-style-type: none"> <li>• Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs.</li> <li>• There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.</li> <li>• Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased.</li> </ul> <p>Useful contacts for patients include:</p> <ul style="list-style-type: none"> <li>○ Sexual health services in Somerset <a href="http://www.swishservices.co.uk">www.swishservices.co.uk</a></li> <li>○ NHS Worth Talking About 0800 282930. <a href="http://www.nhs.uk">Sexual health - NHS (www.nhs.uk)</a></li> <li>○ NHS Direct – 111</li> </ul>
<b>Advice/follow up treatment</b>	<ul style="list-style-type: none"> <li>• The individual should be advised to seek medical advice in the event of an adverse reaction.</li> <li>• The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned.</li> <li>• Pregnancy test as required (see advice to individual above).</li> <li>• Individuals advised how to access on-going contraception and STI screening as required.</li> <li>• 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.</li> </ul>
<b>Records</b>	<p><b>Accredited pharmacists in Somerset are to use the PharmOutcomes system for recording purposes.</b></p> <p>Record:</p> <ul style="list-style-type: none"> <li>• The consent of the individual and</li> <li>• If individual is under 13 years of age record action taken, and to include details of the discussion with the safeguarding expert.</li> <li>• If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.</li> </ul>

	<ul style="list-style-type: none"> <li>• If individual over 16 years of age and not competent, record action taken.</li> <li>• Any safeguarding action taken for vulnerable adults.</li> <li>• Name of individual, address, date of birth</li> <li>• GP contact details where appropriate</li> <li>• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight</li> <li>• Any known drug allergies</li> <li>• Name of registered health professional operating under the PGD</li> <li>• Name of medication supplied</li> <li>• Date of administration</li> <li>• Dose supplied</li> <li>• Quantity supplied including batch number and expiry date in line with local procedures.</li> <li>• Advice given, including advice given if excluded or declines treatment</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns</li> <li>• Any referral arrangements made</li> <li>• Any administration outside the terms of the product marketing authorisation</li> <li>• Recorded that supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p> <ul style="list-style-type: none"> <li>• <b>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 administration of any medication through the PharmOutcomes system.</b> Records should be kept for at least eight years, or for children, until the child is 25 years old.</li> </ul>
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	<ul style="list-style-type: none"> <li>Individuals supplied with medicines or have medicines administered under PGDs are subject to the normal NHS prescription charges and exemptions.</li> </ul> <p><b>Serious events / incidents / near misses</b> - All significant events/incidents/near misses occurring in relation to the administration of a medicine under this PGD must be reported on the relevant incident form in a timely manner.</p>

4. Key References	
Key references (accessed September 2022)	<ul style="list-style-type: none"> <li>Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>NICE Medicines practice guideline “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - March 2017 (Amended July 2023) <a href="#">FSRH Clinical Guideline: Emergency Contraception (March 2017, amended July 2023)   FSRH</a></li> <li>FSRH CEU Statement Response to Edelman 2022 (August 2022) <a href="#">FSRH CEU Statement: Response to Edelman 2022 (August 2022)   FSRH</a></li> <li>Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 <a href="#">FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022)   FSRH</a></li> <li>Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018_ <a href="https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines">https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines</a></li> </ul>



## Registered Health Professional Authorisation Sheet

**Levonorgestrel PGD Version 9    Valid from: 1<sup>st</sup> April 2025    Expiry: 31<sup>st</sup> March 2028**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

### Registered health professional

- By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.
- Patient group directions do not remove inherent professional obligations or accountability.
- It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

**I confirm that I have read and understood the content of this Patient Group Direction and agree to provide the service in accordance with this PGD and that I am willing and competent to work to it within my professional code of conduct**

#### Location:

Name of Professional	Designation / Professional registration no.	Signature	Date

### Authorising manager

**I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD.  
I give authorisation on behalf of: ..... (insert name of organisation) for the above named health care professionals who have signed the PGD to work under it.**

Name	Designation	Signature	Date

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

**Note to authorising manager**

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

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.

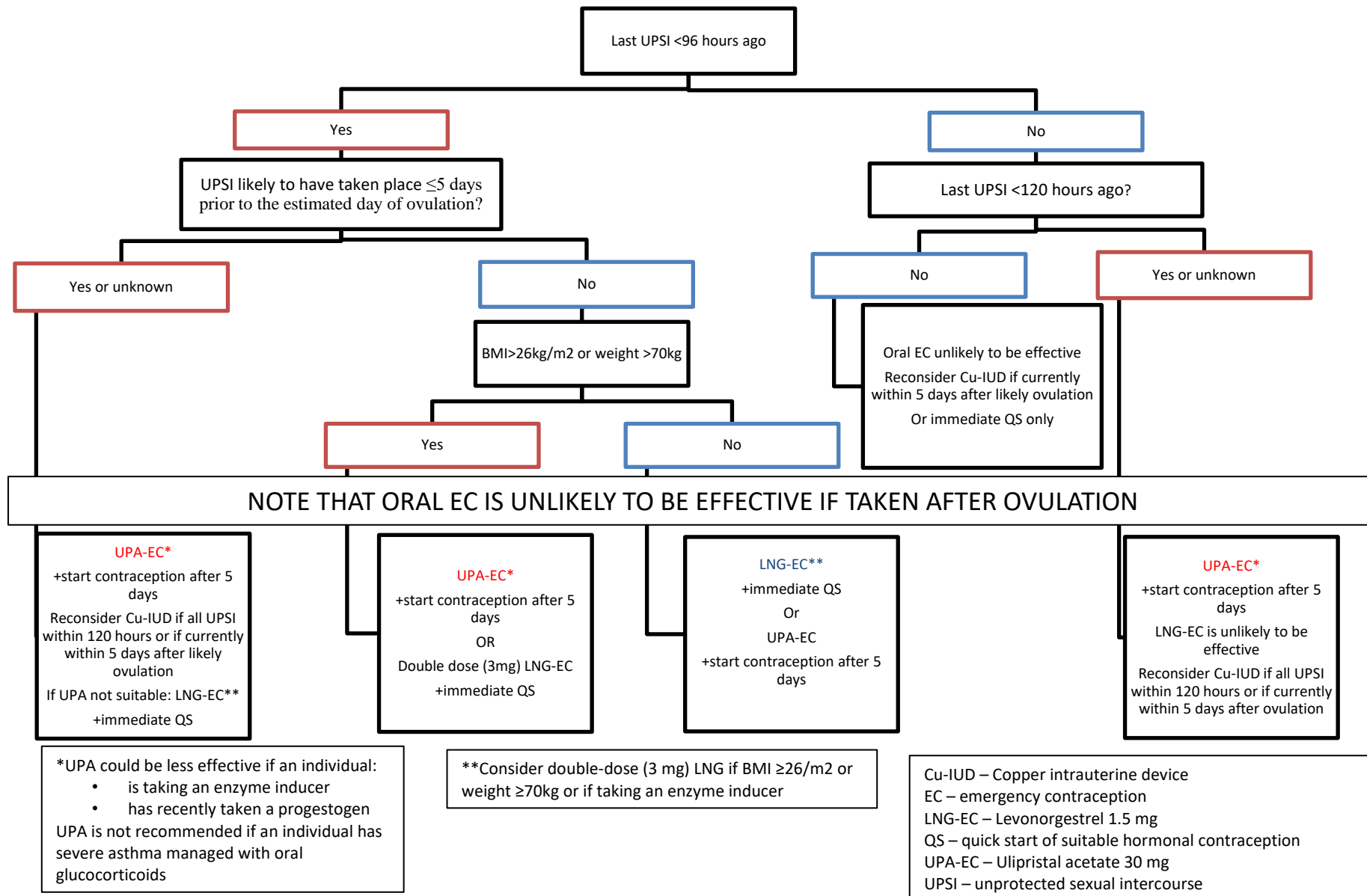
This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

**The PGD must be easily accessible in the clinical setting**

**Pharmacist – please retain signed copy onsite and available for inspection by a Commissioning representative on request.**

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

The CU-IUD is the most effective form of EC. If criteria for insertion of a Cu-IUD are not met or a Cu-IUD is not acceptable to individual, consider oral EC.



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

<b>Format</b>	<b>Programme title</b>	<b>Repeat at least every:</b>
<b>Online workshops</b>	<p><b>Community Pharmacy Somerset, CPPE and Somerset Council Emergency contraception, safeguarding and child exploitation</b> (This is the preferred option - see the CPS bulletin and <a href="#">website</a> for the next date and booking details)</p> <p><b>Or</b></p> <p><a href="#">CPPE Emergency contraception</a></p>	<p>4 years (mandatory)</p> <p><b>Or</b></p> <p>4 years (mandatory)</p>
<b>e-learning</b>	<p><a href="#">CPPE Emergency Contraception</a></p> <p><a href="#">eLearning for healthcare Safeguarding adults Level 2</a></p> <p><a href="#">eLearning for healthcare Safeguarding children Level 2</a></p> <p><a href="#">CPPE Contraception</a></p> <p><a href="#">eLearning for healthcare Patient Group Directions</a></p> <p><a href="#">CPPE Safeguarding children, young people and adults: level 2 case studies for pharmacy professionals</a></p> <p><a href="#">CPPE Consultation skills: what good practice looks like</a></p>	<p>2 years (mandatory)</p> <p>2 years (mandatory)</p> <p>2 years (mandatory)</p> <p>Once (recommended)</p> <p>Once (recommended)</p> <p>Once (recommended)</p> <p>Once (recommended)</p>
<b>e-assessment</b>	<p><a href="#">CPPE Emergency contraception</a></p> <p><a href="#">CPPE Consultation skills for pharmacy practice</a></p> <p><a href="#">CPPE Contraception</a></p>	<p>2 years (mandatory)</p> <p>Once (recommended)</p> <p>Once (recommended)</p>

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](#):

**PharmOutcomes**

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If you are completing the Declaration of Competence system in order to deliver a commissioned service which is supported by [PharmOutcomes](#) you will need to share data relating to your CPPE learning and assessment record.

☒ To allow your data to be shared with PharmOutcomes, ensure this box is ticked.

Save changes

## Appendix 3 Somerset Emergency Contraception Pharmacy Pathway for Young People

Young person aged  
under 18 years old

### Safeguarding / Child Protection

- If there is a child protection concern, discuss with a designated safeguarding lead (refer to current Somerset Safeguarding and CLA Professional Checklist available from [somicb.safeguardingandcla@nhs.net](mailto:somicb.safeguardingandcla@nhs.net)) and refer to **Somerset Direct** (Children's Social Care) on **0300 123 2224**
- Where there is a concern of child sexual exploitation (**CSE**) as above and complete the CSE screening tool
- Where there is a concern regarding female genital mutilation (**FGM**) discuss with a safeguarding lead / if aware that FGM may have occurred report to **101** (FGM mandatory reporting)

Young person aged  
12 years old

Young person aged  
under 12 years old

- EHC can be supplied to females aged 12 years and over via this PGD. However, if a patient is aged under 13 years, advice **MUST** be sought from a child protection expert. Children under 13 cannot consent to sex and so this is statutory rape. A referral needs to be made to **Somerset Direct** on **0300 123 2224**
- If the child is under 12 years of age supply cannot be made and a referral must be made to Somerset Direct as above

Young person aged  
under 16 years old

### Confidentiality and Fraser Guidelines

The age of consent for sex is 16 years old. However, all young people have the right to confidentiality if there are no child protection issues and they meet the [Fraser guidelines](#) i.e.

- the individual understands the information being given to them
- the individual cannot be persuaded to inform their parent(s) / carer(s)
- their mental health will suffer as a result of not receiving the service
- it is in their best interests to receive the service

The need to breach confidentiality should be carefully considered and discussed with the individual and a designated safeguarding lead / child protection expert

Young person aged  
under 25

- If 15-24 years old offer a chlamydia screening kit and advise of risk of STIs due to unprotected sexual intercourse
- Advise on contraception and access to sexual health services / GP, and C-card scheme if under 19
- Provide information on [www.swishservices.co.uk](http://www.swishservices.co.uk) and Swish App

If you are worried about  
a vulnerable adult please  
call 0300 123 2224