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PATIENT GROUP DIRECTION (PGD)

For the supply of Ulipristal Acetate (ellaOne®)

Version:	4
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Approved by:	Trudi Grant, Director of Public Health
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SOMERSET

PATIENT GROUP DIRECTION (PGD)

FOR: The supply of Ulipristal Acetate (ellaOne®)

VERSION CONTROL

Document Status:	Approved
Version:	4

Document Change History		
Version	**Date**	**Comments**
1	06/03/2018	Catherine Falconer first draft
2	19/03/2018	Michelle Hawkes amendments
3	15/05/18	Amendments to include decision making algorithm
4	31/05/18	Amendments advised by Rebecca Myers and Michelle Hawkes

Author	Catherine Falconer
Document reference	

PATIENT GROUP DIRECTION (PGD) FOR

Drug: Ulipristal Acetate 30 microgram tablet (ellaOne®)
Condition: Female adults and children aged 12 years and older requiring emergency hormonal contraception within 120 hours of unprotected sexual intercourse (UPSI)
Professional group: Registered Pharmacists

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**	Female adults and children aged 12 years and older requiring emergency hormonal post-coital contraception (EHC) within 120 hours of unprotected sexual intercourse (UPSI) or failed contraception
2.	**Inclusion criteria**	Female adults and 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 decision making algorithm in appendix 1 **And** *all* the following criteria are met: • The individual had UPSI within the previous 120 hours; • Ulipristal acetate is the most appropriate treatment; • The individual has taken EHC on no more than one previous occasion in the current menstrual cycle; • The individual has received Ulipristal but has vomited within 3 hours of the dose (provided the repeat dose will be taken within 120 hours of UPSI); • 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: 1) Whether the individual 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; • A discussion has occurred with the individual regarding alternative emergency contraception methods - IUD - to allow the individual to make an informed choice, and a referral is

		offered ○ This should include that insertion of an 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 an IUD, provided the individual has presented within 120 hours of UPSI and there are no other contraindications, Ulipristal can still be offered as a precaution (in case the patient misses the appointment) • 21 days or more have elapsed since giving birth
3.	**Exclusion criteria**	• **Aged 25 years or over** • **Any UPSI over 120 hours ago** in this cycle • **Vomiting more than 3 hours after** ingesting Ulipristal - If the individual has received Ulipristal but has vomited *more* than 3 hours after the dose was taken then they do not need to take a repeat dose • **Pregnancy (known or suspected)** • **Known hypersensitivity to Ulipristal or any other ingredient in the formulation** • **Lactose and galactose intolerance** • **Lapp lactase deficiency or glucose-galactose malabsorption** • **Unexplained vaginal bleeding** • **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 as EHC may not be effective • **Women with uncontrolled/severe asthma treated by oral glucocorticoid** • **Anaphylactic reactions** - Any individual who has had a true anaphylactic reaction to Ulipristal, any other progestogen, or any component of Ulipristal tablets, or having shown hypersensitivity after previous administration: see SPC for a full list of excipients • **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 (i.e. supply under this PGD is not allowed through telephone consultations etc.) • **Liver enzyme inducing drugs** – EC is contra-indicated if there is UPSI or barrier failure during, or in the days following, use of liver-enzyme drugs. Offer an IUD (unaffected by liver enzyme-inducing drugs) or a double dose of Levonorgestrel. Ulipristal is not recommended for women taking enzyme inducing drugs, or within 4 weeks of stopping them • **Drugs that increase gastric PH**: antacids, histamine H2 antagonists and proton pump inhibitors • **Training -** Pharmacists who have not completed the

		Somerset County Council (SCC) approved training to be locally accredited as stipulated in the Somerset Pharmacy Emergency Hormonal Contraception Accreditation Process flow chart. This requires: o Being registered as a pharmacist with the GPhC; o Completing and passing the Centre for Pharmacy Practice (CPPE) EHC online module and a Safeguarding children online module within the last two years; o Attending the SCC/CPPE EHC and Safeguarding workshop every 4 years 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
4.	**Cautions / Need for further advice**	**<u>Pregnancy and Breastfeeding</u>** **Pregnancy –** • Ulipiristal should not be taken when suspected or known to be already pregnant – do pregnancy test to check when appropriate • A pregnancy test is advised three weeks after UPSI **Breastfeeding –** • Ulipristal is excreted into breastmilk and the risk to infant is unknown • Do not breastfeed or express milk for storage for 1 week after taking Ulipristal • Advise to express and discard milk to maintain lactation **Drug interactions** • The effectiveness of Ulipristal may be reduced if a woman takes progestogen (including Levonorgestrel emergency contraception) in the week prior to and five days following Ulipristal. Consider IUD or Levonorgestrel in this circumstance • **Other medications** - Consult current BNF for any potential

		interactions • **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) • **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 • **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
5.	**Action if excluded**	• Discuss reasons for exclusion. • For women aged over 25 years discuss/offer alternative emergency contraceptive method including over the counter purchase or referral to GP or sexual health services • If the women 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 Pharmacists discretion. • Immediately refer to patient's GP, sexual health service, or out of hours • Any child protection and safeguarding issue 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

Drug: Ulipristal Acetate 30 microgram tablet (ellaOne®)
Condition: Female adults and children aged over 12 years requiring only emergency hormonal contraception within 120 hours of unprotected sexual intercourse (UPSI)
Professional group: Registered Pharmacists

8.	**Drug Details**	
	Name, form and strength of medicine	Ulipristal Acetate 30mg (ellaOne®)
	Legal Category	Pharmacy Medicine
	Black Triangle Status	None
	Route / method of administration	Oral
	Dosage	One tablet (30 micrograms) as a single dose treatment as soon as is practicable after unprotected sexual intercourse (UPSI). Can be taken at any time during the menstrual cycle, with or without food.
	Frequency	Once as a single dose treatment, except: • If vomiting occurs within three hours of taking the Ulipristal 30mg tablet a second supply of one Ulipristal 30mg tablet may be made AND • All inclusion and exclusion criteria still hold
	Duration of treatment	Single dose treatment
	Total dose number to supply / administer	One 30mg tablet *except:* • If vomiting occurs within three hours of the patient taking Ulipristal 30mg tablet a repeat supply of a second single 30mg tablet is allowed.
9.	**Side effects**	**Common side effects** (these may affect up to 1 in 10 people) • Nausea, abdominal (stomach)) pain or discomfort, vomiting • Painful periods, pelvic pain, breast tenderness • Headache, dizziness, mood swings • Muscle pain, back pain, tiredness The patient should be warned that some common side effects could also be related to an undiagnosed pregnancy (or related complications). Any pregnancy in a woman who has taken ulipristal should be reported to www.hra-pregnancy-registry.com as part of post marketing monitoring.

		Uncommon side effects (these may affect up to 1 in 100 people) • Diarrhoea, heartburn, wind, dry mouth • Unusual or irregular vaginal bleeding, heavy/prolonged periods, premenstrual syndrome, vaginal irritation or discharge, lesser or greater sex drive • Hot flushes • Appetite changes, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, migraine, visual disturbances • Influenza • Acne, skin lesions, itching • Fever, chills, malaise For other less common side effects, refer to the Summary of Product Characteristics and current version of the BNF
10.	**Reporting procedure of Adverse Reactions**	• Any serious adverse reaction to Ulipristal or any of the Ulipristal tablets excipients should be reported to the MHRA/CSM using the "yellow card" system. The patient's doctor, if known, must also be informed • 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.	**Advice to patient / carer**	• There is no day of the menstrual cycle when there can be certainty that unprotected sexual intercourse (UPSI) would not result in pregnancy • If postpartum, ovulation does not occur until day 27 therefore contraception is only required from day 21 • After taking EHC, menstrual periods are often normal and occur at the expected date, however, they can sometimes occur earlier or later than expected by a few days • If menstrual periods are delayed by more than 5 days, or abnormal bleeding occurs (e.g. light, heavy or brief) at the expected date of menstruation, or if pregnancy is suspected for any other reason, the patient should seek further medical advice for further investigation and to exclude pregnancy • For patients taking the Combined Oral Contraceptive Pill, if no withdrawal bleed occurs in the next pill-free period following the use of EHC, the patient should seek medical advice as further investigation maybe required and to rule out pregnancy • When Ulipristal is given as emergency contraception the effectiveness of combined hormonal and progestogen – only contraceptives may be reduced- additional precautions (barrier methods) required for 14 days for combined and parenteral progestogen-only hormonal

		contraceptives (16 days for Qlaira®) and 9 days for oral progestogen-only contraceptives • Patients should be advised not to quick start a new oral contraception for at least 5 days after taking Ulipristal as an emergency contraceptive (FSRH) • The earlier Ulipristal is taken after UPSI the greater the efficacy • Advice that the oral EHC may be less effective if the individual has a higher weight or BMI • Inform individual of common side-effects (see Section 9 and refer to current version of BNF and SPC) • If vomiting occurs for any reason within three hours of taking the tablet, the patient should seek to obtain another supply of Ulipristal as soon as possible • The patient should be advised to make a medical appointment to initiate or adopt a method of regular contraception if appropriate • If a third repeated administration of Ulipristal is required within a menstrual cycle the patient needs to be referred to their GP, sexual health service, or Out of Hours (OOH) service • If pregnancy occurs after treatment with Ulipristal, the possibility of ectopic pregnancy should be considered, although the absolute risk is low • Ectopic pregnancy may continue despite the occurrence of uterine bleeding. Therefore patients need to exclude the possibility of pregnancy three weeks after receiving Ulipristal • Prior to treatment, the patient (or person with parental responsibility) is given the Patient Information Leaflet from the product packaging. Confirmation must be sought that they have read and understood it and consent to treatment • Ulipristal is secreted into breast milk. Potential exposure of an infant to Ulipristal can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing following Ulipristal administration for 7 days. Express and discard milk to keep supply up • Ulipristal is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure. All patients who present for emergency contraception should be given information about other methods of contraception and about the benefits of long-acting reversible contraception (NICE QS 129) • Use of emergency contraception does not replace the necessary precautions against sexually transmitted infections – the use of condoms must be promoted • Useful contacts for patients include: ○ FPA UK (formerly Family Planning Association) –

		0845 122 8690 ○ NHS Direct – 111 ○ Sexual health services in Somerset www.swishservices.co.uk ○ Downloading the Somerset young people's sexual health app (Swish app)
12.	**Arrangements for follow up**	• There is no requirement for follow up within the pharmacy • 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 is enhanced: the patient should be referred to their treating doctor 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 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 ellaOne 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
Specialist competencies or qualifications		• Registered pharmacists must be locally accredited and provide a Declaration of Competence (DOC) demonstrating: • Successful completion of CPPE online training module for EHC, to be refreshed every 2 years • Successful completion of CPPE (or equivalent) online training module for Level 2 Safeguarding Children, to be refreshed every 2 years

	• Attendance at Somerset County Council and CPPE workshop on EHC and Safeguarding (or SCC approved equivalent), to be refreshed every 4 years
Continued education & training	• It is recommended that pharmacists also complete the CPPE consultation skills e-learning and / or distance learning • 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 • Pharmacists should supervise the client taking the Ulipristal tablet particularly if they have concerns (i.e. about frequent requests or that may be being obtained for another person) • The pharmacist must be able to access this PGD when needed

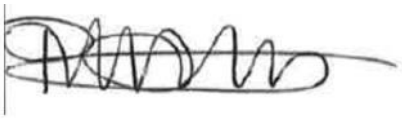
References used in this PGD

- NICE PGD Good Practice Guidance, 2013 (updated July 2015) https://www.nice.org.uk/guidance/mpg2/resources/patient-group-directions-1779401941189
- BNF No.70, September 2015
- 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
- ellaOne 30mg Product characteristics. Accessed on 5th February 2018. https://www.medicines.org.uk/emc/product/6657
- Faculty of Sexual and Reproductive Health. *Missed Pill Recommendation*. 2011. www.fsrh.org/pdfs/CEUStatementMissedPills.pdf
- Faculty of Sexual and Reproductive Health, Clinical Effectiveness Unit. *Emergency Contraception*. August 2011 (updated January 2012) http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf
- UKMEC UK Medical Eligibility Criteria for Contraceptive Use 2009 www.fsrh.org/pdfs/UKMEC2009.pdf
- Family Planning Association. The combined pill- your guide http://www.fpa.org.uk/sites/default/files/the-combined-pill-your-guide.pdf
- Family Planning Association. The progesterone only pill- your guide http://www.fpa.org.uk/sites/default/files/progestogen-only-pill-your-guide.pdf
- Faculty of Sexual and Reproductive Healthcare (FSRH). FSRH Guideline. Emergency Contraception. March 2017 (updated May 2017). https://www.fsrh.org/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

PATIENT GROUP DIRECTION (PGD) FOR:

Drug: Ulipristal Acetate 30 microgram tablet (ellaOne®)
Condition: Female adults and children aged 12 years and older requiring emergency hormonal contraception within 120 hours of unprotected sexual intercourse (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	Andrew Tresidder DR. ANDREW TRESIDDER GP. GMC 2823735	29 May 2018
Director of Public Health	 Trudi Grant, MSc PH, UKPHR, FFPH	29 May 2018
Senior Pharmaceutical Advisor	 REBECCA MYERS 2049387	29 May 2018
Consultant Microbiologist **(for Antibiotics)**		

PATIENT GROUP DIRECTION (PGD) FOR

Drug: Ulipristal Acetate 30 microgram tablet (ellaOne®)
Condition: Female adults and children aged 12 years and older requiring emergency hormonal contraception within 120 hours of unprotected sexual intercourse (UPSI)
Professional group: Registered Pharmacists
Professional Group:

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.

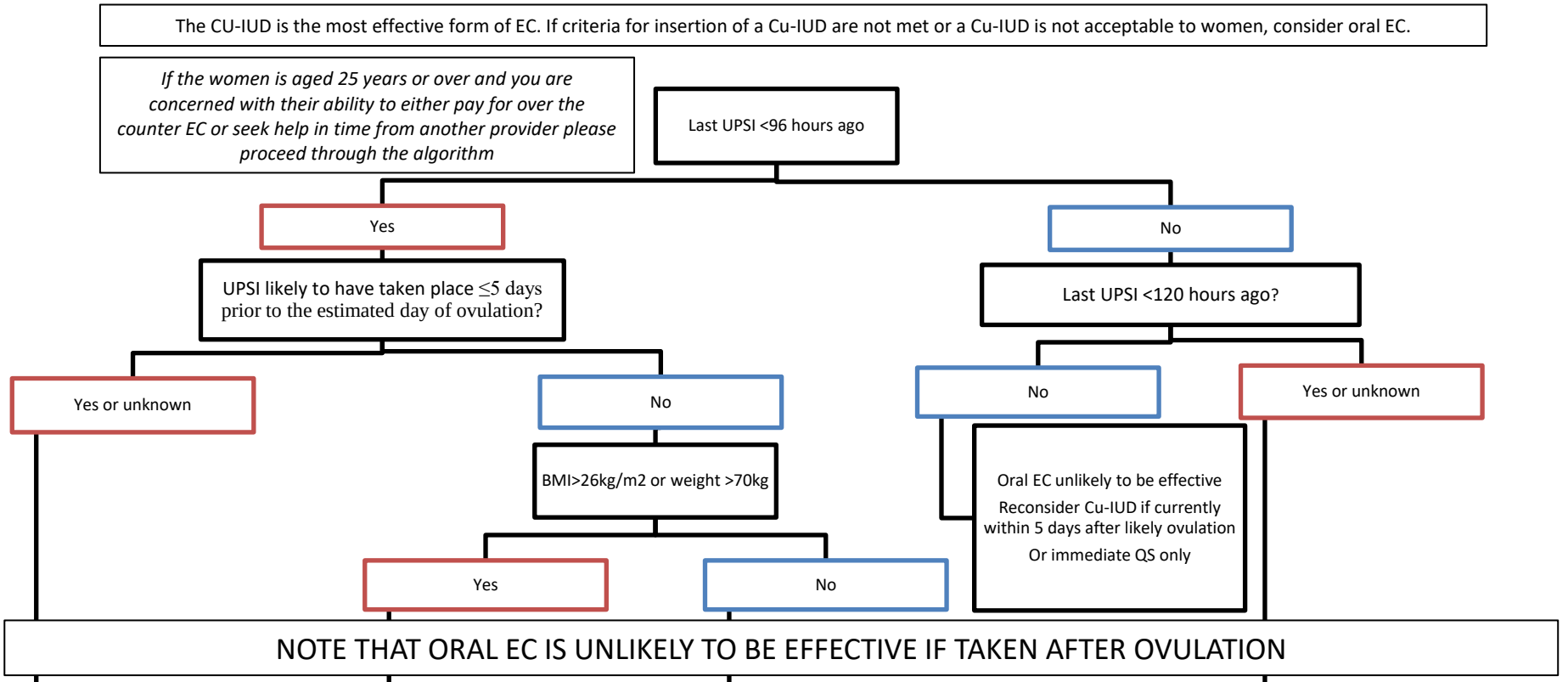
I have read and understood the Patient Group Direction and agree to supply / administer this medicine only in accordance with this PGD.

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 (LG-EC) VS Ulirpristal Acetate EC (UPA-EC)



*UPA could be less effective if:

- A women is taking an enzyme inducer
- A women has recently taken a progestogen

UPA is not recommended if a women has severe asthma managed with oral glucocorticoids

**Consider double-dose (3 mg) LNG if BMI >26/m2 or weight >70kg or if taking an enzyme inducer

Cu-IUD – Copper intrauterine device
EC – emergency contraception
LNG-EC – Levonorgestrel 1.5 mg
QS – quick start of suitable hormonal contraception
UPA-EC – Ulipristal acetate 30 mg
UPSI – unprotected sexual intercourse