PATIENT GROUP DIRECTION (PGD)

Pharmacist or Nurse supply and/or administration of

Ulipristal acetate 30mg tablet for emergency hormonal contraception (EHC) in Primary Care in Gloucestershire

Developed in partnership with the Sexual Health Service (Gloucestershire)

Documentation details

Reference no:	PGD Ulipristal Sept 21
Version no:	2021-2023 v1
Valid from:	1/10/2021
Review date:	Sept 2021
Expiry date:	30/09/2023

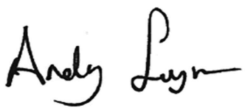
Change history

Version number	Change details	Date
2021-2023 v1	• Updated hyperlinks and reference dates • Updated as per FSRH Dec 2020 changes • Changes to include those recommended on SPS website https://www.sps.nhs.uk/articles/reproductive-health-patient-group-direction-pgd-templates/ • Changes to authorisation section and section 7	Sept 2021
2019 - 2021 v1	• FSRH Guidance Dec 2017 referenced • References updated e.g. New NMC Code 2015 (updated 2018) • New standards for administration of medicines and developed by NMC and the Royal Pharmaceutical Society (GB)(RPS) added • Safeguarding contact details updated • Addition of information on Pregnancy Advisory Service • Pharmacist training reflects the service specification	Sept 2019
2017 - 2019 v1	• Revision in light of UKMEC 2016 guidance and FSRH emergency contraception guidance 2017. • Inclusion of Fraser Guidelines Assessment • Addition of Safeguarding training requirement • Updated Summary of Product Characteristics (SPC) and references	Oct 2017

Version number (continued)	Change details	Date
2015 – 2017 v 2	• Addition of new NMC Code 2015 • Additional information around competent children declining to provide consent. • Addition of updated FSRH guidance for quick starting contraception • Interactions list updated • Breastfeeding recommendations updated • NMC consent reference added • Revision of decision-making flow chart – now separate document from Sexual Health Services • Removal of reference to brand name	Dec 2015
2014 – 2016	• Reviewed/updated	Mar 2014

1. PGD development and authorisation

This PGD has been developed and authorised for use by the following health professionals on behalf of NHS Gloucestershire Clinical Commissioning Group (GCCG) and Gloucestershire County Council (GCC):

Developed by:	Name	Signature	Date
Pharmacist	NHS Gloucestershire CCG Deputy Director of Quality Teresa Middleton		7.10.2021
Doctor	NHS Gloucestershire CCG Clinical Chair Dr Andrew Seymour		7.10.2021
Nurse	NHS Gloucestershire CCG Executive Nurse and Quality Lead Dr Marion Andrews-Evans		07.10.21
Public Health	Gloucestershire County Council Executive Director of Adult Social Care and Public Health Prof. Sarah Scott		6.10.21

This document has been written and authorised on the understanding that it remains in its entirety with no additions, omissions or alterations.

All information contained within this document was correct at the time of going to press. It is acknowledged that systems and processes change over time and that new drugs may be introduced. As licences vary, if a new brand is introduced it will not necessarily be covered within its corresponding PGD. If there are changes to practice, or the need for more PGDs to be developed, please contact the Head of Medicine Management at NHS Gloucestershire Clinical Commissioning Group (CCG).

This PGD has been peer reviewed by the GCCG PGD Working Group

PGD Working Group Membership

Name	Designation
Teresa Middleton	NHS Gloucestershire CCG Deputy Director of Quality
Andrew Seymour	NHS Gloucestershire CCG Clinical Chair
Marion Andrews-Evans	NHS Gloucestershire CCG Executive Nurse and Quality Lead
Julie Symonds	NHS Gloucestershire Deputy Director of Nursing
Liz Ponting	NHS Gloucestershire CCG Senior Medicines Optimisation Pharmacist

Additional Advice From	
Louise Plumridge	Specialist Pharmacist HIV & Sexual Health Gloucestershire Health and Care Services NHS Foundation Trust
Madhusree Ghosh	Consultant Sexual and Reproductive Healthcare Gloucestershire Health and Care Services NHS Foundation Trust
Evelyne Beech	IP Pharmacist with Special Interest, St Catherine's Surgery, Cheltenham
Helen Acock	NHS Gloucestershire CCG Clinical Learning and Development Matron

2. Organisational authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.
It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD. The signatories above in section 1 authorise this PGD for use by practitioners as outlined below

Gloucestershire County Council/NHS Gloucestershire Clinical Commissioning Group authorises this PGD for use by the services or providers listed below:
Practitioners who are: • Contracted through a current signed Service Specification with Gloucestershire County Council for the provision of Advanced Contraceptive Services in Community Pharmacy and act in accordance with the requirements of this specification. • Practice Nurses within Gloucestershire (where PGD has been adopted by the surgery)
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by Gloucestershire County Council and NHS Gloucestershire Clinical Commissioning Group must be used.

Any concerns regarding the content of this PGD should be addressed to: glccg.medicines@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets/templates may be used where appropriate in accordance with local policy

3. Characteristics of staff

Qualifications and professional registration	Registered Professional E.g. RN with current NMC registration, or pharmacist registered as a practising pharmacist with GPhC GB.

Initial training	All practitioners must have read and understood, and act in accordance with appropriate professional guidance e.g.:
	The Medicines and Healthcare Products Regulations Agency 2017 https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them
	The NMC Code of professional standards of practice and behaviour for nurses, midwives and nursing associates (updated 2018) https://www.nmc.org.uk/standards/code/,
	Professional guidance on the safe and secure handling of medicines, developed by NMC and the Royal Pharmaceutical Society (GB)(RPharmS) GPhC Standards for pharmacy professionals
	In addition, all practitioners must:
	• Sign the signature sheet for the PGD
	• Have undertaken appropriate training to carry out clinical assessment of patient leading to the provision of EHC according to the indications listed within this PGD (e.g. E- Learning for Healthcare modules 3 and 4: see references)
	• Be able to demonstrate competencies and be up to date with current contraceptive methods and research (may be self-directed).
	• Have completed self-directed training on safeguarding (e.g. CPPE modules on safeguarding children and vulnerable adults).
	Pharmacists must also:
	• Have completed and submitted a declaration of competence (DOC) (uploaded to PharmOutcomes)
	• Meet the training requirements specified in the Service Specification for Advanced Contraceptive Services in Community Pharmacy * see footnote);
	*Foot note **
	At the time of revision, the GCC Service Specification for Advanced Contraceptive Services in Community Pharmacy stated the information below with regard to training requirements
	• *Have an up to date Centre for Pharmacy Postgraduate Education (CPPE) Declaration of Competence (DOCs) for emergency contraception; and ensure they are reaccredited every two years;*
	• *Attend a face to face CPPE Emergency Contraception event at least every four years;*
	• *Have completed the following CPPE modules:*
	  ○ *Consultation skills for pharmacy practice*
	  ○ *Contraception*
	  ○ *Emergency contraception*
	  ○ *Sexual health in pharmacies*
	  ○ *Safeguarding children and vulnerable adults: Level 2*
	  ○ *Safeguarding children and vulnerable adults: a guide for the pharmacy team or level 2 safeguarding or the equivalent*
	• *Attend a **face to face** local safeguarding training event covering children and vulnerable adults at least every four years.* Please check current Service Specification for the most up to date information

Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions For the most up to date guidance please refer to sexual & reproductive health website www.fsrh.org ***Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.***
Ongoing training and competency	Pharmacists: • Have an up to date Centre for Pharmacy Postgraduate Education (CPPE) Declaration of Competence (DOCs) for emergency contraception; and ensure they are reaccredited every two years; • Attend a face to face CPPE Emergency Contraception event at least every four years • Attend a face to face local safeguarding training event covering children and vulnerable adults at least every four years Nurses: • Be able to demonstrate competencies and be up to date with current contraceptive methods and research (may be self-directed).
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly. **For choice of emergency contraceptive method refer to FSRH emergency contraception decision making algorithm** https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ amended Dec 2020 (also Appendix 2 at the end of the PGD – ensure using the latest version by checking FSRH website)
Criteria for inclusion	• Any individual of reproductive age 13 years or over (Where those aged 13 to 15 years are Fraser competent) presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. • No contraindications to the medication. • Informed consent given • **and** when a copper intrauterine device (IUD) has been discussed and accepted or declined (see below where IUD not immediately available) (Patients who have already been treated but who vomited dose within 3 hours and attend for re-treatment) Continued

Criteria for inclusion (continued)	Ulipristal emergency contraception may be repeated if a woman has already received Ulipristal emergency contraception earlier in the same menstrual cycle. If IUD not immediately available, continue to supply and refer to appropriate health service provider **Note:** Where clients are believed to be under 16 years of age (and at least 13 years or over) they must be assessed using Fraser guidelines and the relevant assessment form completed (see Appendix 3 at the end of the PGD) If there are safeguarding concerns regarding the Client, refer to the guidance on G-Care website contact safeguarding team (details below on Fraser check list Appendix 3)
Criteria for exclusion	• Informed consent not given. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Less than 13 years of age; refer to GP or sexual health service for further advice (Tel. 0300 421 6500 www.hopehouse.nhs.uk). Consider risk of any safeguarding issues and report as necessary. • This episode of UPSI occurred more than 120 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 120 hours. • Known or suspected 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). • 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 • Use of levonorgestrel or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications). • Concurrent use of antacids, proton-pump inhibitors or H_2-receptor antagonists. • Severe asthma controlled by oral glucocorticoids. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping. • Acute porphyria • The client requires quick start earlier than the required 5 day delay following Ulipristal EHC dose. See FSRH Quick Start Clinical Guideline • Inability to swallow tablets • Lactose intolerance • Unexplained vaginal bleeding Continued

Criteria for exclusion (continued)	• Current breast cancer • Severe malabsorption (e.g. Crohn's disease) • UPA is not recommended for women with UPSI or barrier failure during or in the 28 days following use of liver enzyme inducing drugs/ herbal products, where their usual contraceptive method is combined hormonal contraception (CHC), progestogen-only pill (POP) or progestogen-only implant. *{Offer a Cu-IUD (unaffected by liver enzyme-inducing drugs) or a double dose (3 mg) of Levonorgestrel if appropriate see Levonorgestrel PGD* **Please note:** this list is not exhaustive for a full list of possible liver enzyme inducers see: • FSRH Guidance: Drug Interactions with Hormonal Contraception (January 2017, last reviewed 2019) **Other drug interactions see**: • Interactions section of the BNF *'Interactions section'* • Summary of Product Characteristics at www.emc.medicines.org.uk See also the 'Drug interactions' section below regarding recent progesterone containing oral contraception (including EHC) and FSRH flow chart at the end of the PGD (pages 15 & 16)
Cautions including any relevant action to be taken	• 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 supply oral EC and refer to the appropriate health service provider. • Ulipristal is ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a repeat dose may be given. • Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. • 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 ulipristal 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. • Breast feeding – advise to express and discard breast milk for 7 days after ulipristal dose. • The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section 'Written information and further advice to be given to individual'. • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. • If the individual has not yet reached menarche, consider onward referral for further assessment or investigation.

Action to be taken if the individual is excluded or declines treatment	• 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 and/or provide them with information about further options. • Patients who are excluded under this PGD should be referred to GP or sexual health service for further advice (Tel. 0300 421 6500; www.hopehouse.nhs.uk) **NB** Adults are classified as 18 years of age or over
Arrangements for referral for medical advice	• Contact the Sexual Health Service doctor on call if more information or advice is required (Sexual Health Services Booking Line:0300 421 6500) or when further sexual health or contraceptive follow up is required Sexual health services are provided from Hope House at Gloucester Royal Hospital and from The Milsom Centre 8 Milsom St, Cheltenham GL50 4BA. There are also community sexual health clinics situated across the county which patients may be triaged into by the sexual health team, if appropriate. For up to date information on local sexual health services, patients should be directed to www.hopehouse.nhs.uk Pregnancy Advisory Service: The Pregnancy Advisory Service is based at Hope House in Gloucester Royal Hospital and offers support for women who have become pregnant and are unsure of what to do. https://www.hopehouse.nhs.uk/pregnancy-advice/ tel:0300 421 6532.

5. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet
Legal category	P
Route / method of administration	Oral - self administration
Indicate any off-label use (if relevant)	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: Lapp-lactase deficiency Hereditary problems of galactose intolerance Glucose-galactose malabsorption Severe hepatic impairment Drugs 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.
Dose and frequency of administration	One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI.
Duration of treatment	A single dose is permitted under this PGD. If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD. Repeated doses can be given within the same cycle. Please note: If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal) If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)
Quantity to be supplied	Appropriately labelled pack of one tablet.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org
Identification & management of adverse reactions	If vomiting occurs within 3 hours: the dose will need to be repeated. If an adverse reaction occurs: • Stop treatment • Inform patient's GP, OOH's GP or emergency services as soon as possible • Document details • Give patient advice on how to manage and recognise adverse reactions A detailed list of adverse reactions is available in the SPC, 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 ulipristal acetate (but may not reflect all reported side effects): • Nausea or vomiting • Abdominal pain or discomfort • Headache • Dizziness • Muscle pain (myalgia) • Dysmenorrhea • Pelvic pain • Breast tenderness • Mood changes • Fatigue • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.

Management of and reporting procedure for adverse reactions	Healthcare professionals and patients/carers 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 patient's medical record. • Report any adverse reactions via organisation incident policy.
Written information and further advice to be given to individual	• 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. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. 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. **Over 16s can order free STI testing kits via the Hope House website: www.hopehouse.nhs.uk (posted out discreetly wrapped). If any sexually transmitted infection is suspected direct patient to their GP or the Sexual Health Service (www.hopehouse.nhs.uk; call 0300 421 6500). Under 16s should be advised to contact Hope House for STI testing.**

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. Direct to Hope House sexual health services website and FPA leaflet on emergency contraception; Contraception-your-guide.pdf http://www.hopehouse.nhs.uk/
Records	**Pharmacists should inform individuals how their personal data will be stored and used.** A record of administration / supply should be made on patient clinical/medication record/PharmOutcomes. This should include: • Name or clinic number and date of birth • that valid informed consent was given – if individual is under 16 years document that they meet Fraser Guidelines • Date of last menstrual period and hours since UPSI • Date and time of administration/supply • Name of drug • Dose, form and route of supply/administration • Quantity supplied/administered • Frequency Route of administration • Batch number and expiry date • Side effects (if any) • Contra-indications and medical advice • Referral arrangements • name of registered health professional • Address • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) • Signature or computerised entry recorded by the practitioner working under this PGD (using an individual protected password) • **Complete a Fraser Guidelines assessment form for all individuals under 16 years** (Appendix 3) Records should be signed and dated (or a password-controlled e-records). All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
Consent	All women for whom treatment is proposed should give their valid consent to treatment at the time of administration Written consent or documented verbal consent must be obtained before the supply of Ulipristal. A record of consent must be maintained for all patients For consent to be valid, the patient or person with parental responsibility must: • be competent to take the particular decision • have received sufficient information to take it • not be acting under duress Continued

Consent (continued)	**Anybody aged 18 years or over (adult)** is assumed to be capable of making decisions unless there is reasonable doubt. **Anybody aged 16 years or 17 years (young person)** is also assumed to be capable of making decisions unless there is reasonable doubt. If the requirements for valid consent are met, it is not legally necessary to obtain consent from the person with parental responsibility for the young person. It is however good practice to involve the young person's family in the decision-making process, unless the young person specifically wishes to exclude them. If a person aged 16 or 17 years gives valid consent to treatment the person with parental responsibility cannot override that consent. **Anybody less than 16 years of age (child)** is not automatically assumed to be capable of making decisions. That capacity to make decisions is related to their maturity and level of understanding in relation to each decision, rather than their age. **For inclusion in PGDs for contraception only**- 'Children under 16 years of age who are considered competent in accordance with the Fraser Guidelines and understands fully what is involved in their proposed procedure can give valid consent and additional consent by a person with parental responsibility is not required. The decision of a competent child to accept treatment can then not be over-ridden by the person with parental responsibility for the child. It is however good practice to involve the child's parents in the decision-making process but take into account the wishes of a competent child about that involvement. The refusal of treatment by a patient less than 18 years of age might be overruled even if he/she is competent, if the treatment is deemed in his/her best interest. Anyone who lacks capacity is treated in his or her best interests. Only people with 'parental responsibility' are entitled to give consent on behalf of their children until they achieve Fraser competence. For young people and children aged 16 and below it is recommended when possible to involve the person with parental authority in the decision regarding consent Healthcare professionals need to carefully document the consent that is obtained (Appendix 3). Any queries need to be discussed with an experienced colleague or sexual health services. For further guidance please refer to the Department of Health document consent for examination or treatment (second edition) DH 2009. Gateway reference 11911 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf GPhC guidance on consent (latest) https://www.pharmacyregulation.org/search/site/consent

Records for Community Pharmacy (to also allow audit trail)	The EHC proforma must be completed (whether EHC is supplied or not) via PharmOutcomes. Claims are triggered (or generated) via PharmOutcomes proforma. *Patient medical records must be kept for 8 years, or if under 16 years until aged 25.* **Complete a Fraser Guidelines' assessment form for all individuals under 16 years** (Appendix 3)

6. Key references

Key references	• 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 • FSRH clinical guidance: www.fsrh.org • FSRH Quick Start Guideline; https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/ • NHS Gloucestershire Clinical Commissioning Group Policies • The Human Medicines Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1916/schedule/16/part/1/made • Medicines Healthcare products Regulation Agency Guidance Patient Group Directions and who can use them (2017) https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • The NMC Code of professional standards of practice and behaviour for nurses, midwives and nursing associates (updated 2018) https://www.nmc.org.uk/standards/code/, • Professional guidance on the safe and secure handling of medicines, developed by NMC and the Royal Pharmaceutical Society (GB)(RPS) • Professional guidance on the administration of medicines in healthcare settings developed by the Royal College of Nursing (RCN) and RPS • Advisory guidance on administration of medicines by nursing associates from Health Education England • (The Nursing and Midwifery Council: Standards for Medicines Management 2007 were withdrawn in Jan 2019) • The latest GPhC Standards for pharmacy professionals (http://www.pharmacyregulation.org/standards) • FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (January 2017, last reviewed 2019) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • E- Learning for Healthcare; Sexual and Reproductive Health https://www.e-lfh.org.uk/programmes/sexual-and-reproductive-healthcare/ (Module 8 – Contraceptive Choices and Module 10 – Emergency Contraception) • SPS website https://www.sps.nhs.uk/articles/reproductive-health-patient-group-direction-pgd-templates/

7. Registered health professional authorisation sheet

PGD Name/Version: Ulipristal (v1) **Valid from**: 1/10/21 **Expiry**: 30/09/2023

Before signing this PGD, check that the document has had the necessary authorisations (Section 2) Without these, this PGD is not lawfully valid**. Please note**: All practitioners using the PGD should retain a 'fully signed' copy for their personal use/files

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**.** Tasks under this PGD cannot be delegated to anyone else.
If this is an update or replacement PGD please ensure that all older versions are withdrawn from use with immediate effect. It is your responsibility to make sure you are using the current version**.**
The most recent versions of PGDs can be accessed via CCG LIVE

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Note to provider authorising manager: Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation**.**

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

Provider 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 provider organisation) ……...(insert address of provider organisation) **for the above-named health care professionals who have signed the PGD to work under it.**			
Name	**Designation**	**Signature**	**Date**

To Pharmacy Contractor:

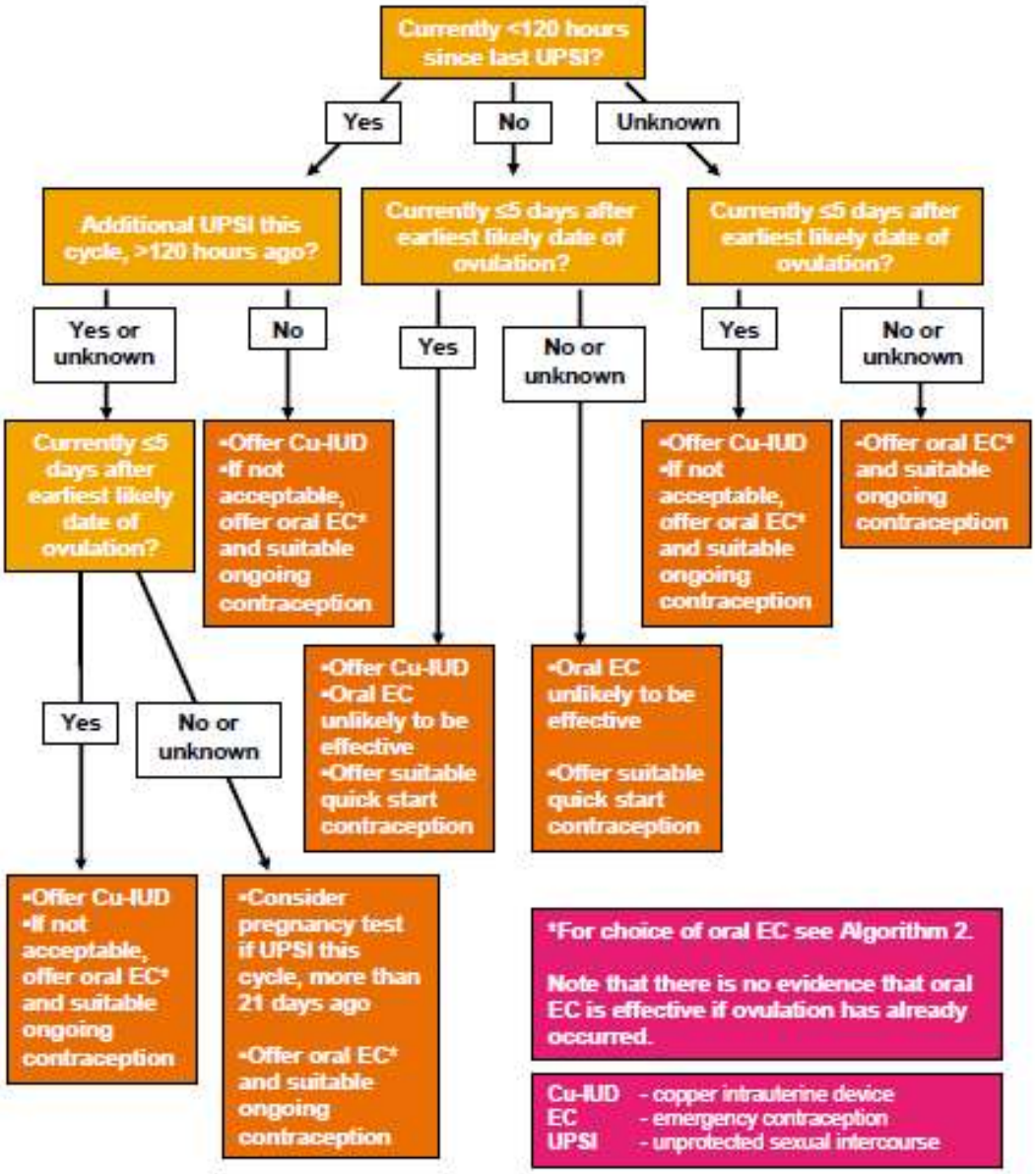
- Please retain one completed copy of this page for your files**.**
- Please email one scanned copy of this completed page
  To publichealth@gloucestershire.gov.uk
  Please mark emails "FAO Vikki Clarke - EHC"

Appendix 2 - FSRH Decision making algorithms

FSRH

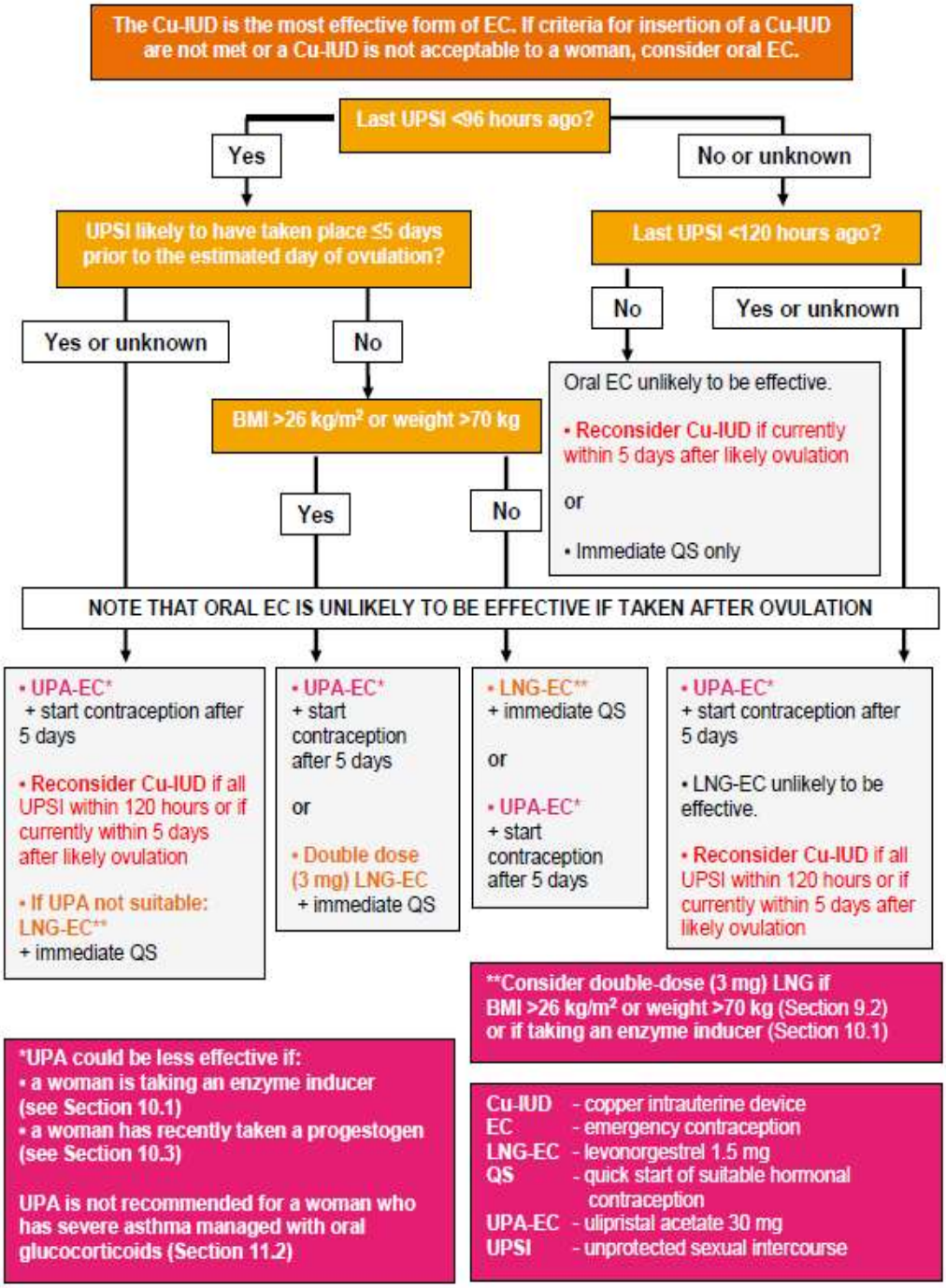
Decision-making Algorithms for Emergency Contraception

Algorithm 1: Decision-making Algorithm for Emergency Contraception (EC): Copper Intrauterine Device (Cu-IUD) vs Oral EC



FSRH

Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)



Appendix 3: Fraser Guidelines Questionaire *(relating to contraception)*

1. The young person understands the advice being given.
2. The young person cannot be convinced to involve parents/carers or allow the medical practitioner to do so on their behalf.
3. It is likely that the young person will begin or continue having intercourse with or without treatment/contraception.
4. Unless he or she receives treatment/contraception their physical or mental health (or both) is likely to suffer.
5. The young person's best interests require contraceptive advice, treatment or supplies to be given without parental consent.

COMMUNITY PHARMACY LOCALLY ENHANCED SERVICES FOR CLIENTS WHO ARE BELIEVED TO BE UNDER 16 YEARS OF AGE

Any Pharmacy Staff having a discussion with the young person should gently explore the following issues at each consultation. This should be fully documented and should include an assessment of the young person's maturity, and whether they are acting voluntarily.

YOUR ASSESSMENT OF FRASER	YES	NO
Understanding of advice given		
e.g. understands the service they are accessing; understands what actions they need to take during or following access to the service. **Notes: (***please record discussion)*		
Encouraged to involve parent / carer		
e.g. client not prepared to talk to parent/carer at this time but will try to do so in due course. May be able to discuss with another responsible adult. Any coercion? **Notes:**		
The effect of physical or mental health of young person if advice / treatment withheld		
e.g. advice/ treatment/ service is needed now, to ensure their wellbeing. **Notes:**		
Action in the best interest of the young person		
e.g. providing the professional service/ advice at this time is in the best interest of the client, regardless of parental consent. **Notes:**		

If the answer to each of these questions is **'YES'** then the service may be supplied.

If a child is not competent to give consent i.e. a '**NO'** to the questions, you should seek consent from a person with "parental responsibility" (this will often, but not always, be the child's parent/ carer).

Pharmacist's/ Staff member's Signature: … … … … … … … … … … … … … … … … …

Date: … ..

Client's Name …

Service Provided …

Please retain this completed document for your record /service file – electronically or as hard copy

Safeguarding Team contact details:

Adult safeguarding: 01452 426868 Socialcare.enq@gloucestershire.gov.uk

Children's safeguarding: 01452 42 6565 childrenshelpdesk@gloucestershire.gov.uk