Northumbria Healthcare NHS Foundation Trust Patient Group Direction for the administration or Supply of **ULIPRISTAL ACETATE (EllaOne®) as Emergency Hormonal Contraception by Community Pharmacists**	PGD: CP02 Version: 02 Issue Date: 6th Sept 2017 Expiry Date: 31st Aug 2020

Registered Practitioners commissioned by Northumbria Healthcare NHS Foundation Trust are entitled to provide the stated medicine without medical prescription under this patient group direction.

Clinical condition or situation to which this PGD applies	
Clinical condition or situation	Request for emergency contraception, following an assessment of pregnancy risk See decision making algorithms for guidance as to most effective method – see appendix 1 and 2 The copper IUCD is the most effective method of emergency contraception and all women should be assessed for and offered this method as first line. If a woman is referred for a copper IUCD oral EC should be given at the time of referral in case the IUCD cannot be inserted or the woman changes her mind Ulipristal Acetate is more effective than Levonorgestrel and should be used first line when the assessed pregnancy risk is higher i.e. within 5 days of expected ovulation date or patient weighing over 70 kg (see appendix 1 and 2)

Criteria for inclusion	• Any female in her reproductive years (minimum age 13 years)
	• Emergency contraception up to 120hrs after first episode of unprotected sexual intercourse (UPSI) that cycle including (but not limited to):
	  ○ Penetration without ejaculation or ejaculation on external genitals
	  ○ Barrier method failure – cap or condom
	  ○ Potential intrauterine contraceptive device (IUD) failure, e.g. lost threads
	  ○ Withdrawal method used
	  ○ No method used
	  ○ Following rape or sexual assault
	  ○ Intrauterine contraception removed after recent intercourse
	• On any day of a natural menstrual cycle
	• From day 21 post partum (unless criteria for lactational amenorrhoea are met - fully breastfeeding, amenorrhoeic and within 6 months of delivery)
	• From day 5 after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD)
	• Patient has received Ulipristal acetate (ellaOne®) but has vomited within THREE hours - offer a repeat dose of Ulipristal acetate (ellaOne®) provided she is still within 120 hours of UPSI.
	• Fraser competent if under 16
	• Patient who may not need emergency contraception on medical grounds on the basis of failed contraception but show extreme anxiety about conceiving

Criteria for exclusion[1]	• Known allergy to the active ingredient ulipristal or any excipients. • Under 13 years. • Patient has previously experienced any severe clinical problems with hormonal contraception • Lactose and galactose intolerance • Lapp lactase deficiency or glucose-galactose malabsorption • Women taking enzyme inducing drugs (and for 4 weeks after stopping); Enzyme inducing drugs include: barbiturates, primidone, phenytoin, carbamazepine, phenylbutazone, St John's Wort, rifbutin, rifampicin or ritonavir. See BNF for full list of affected drugs. • Pregnancy (where pregnancy is suspected, a pregnancy test should be performed). • Unexplained vaginal bleeding. • Acute porphyria. • Severe asthma controlled by oral glucocorticoids due to antiglucocorticoid effect of UPA • Individuals under 16 years of age and not competent using the Fraser guidelines unless appropriate adult can consent for them • Patients refusing treatment under this PGD • Patient requests to see a doctor • Patient is not competent to give consent under the Mental Capacity Act • Third party requests • Not to be taken within 7 days of LNG-EC • Has used hormonal contraception in the preceding 7 days, including injection or implant still in situ but expired • If considering quick starting contraception LNG may be preferable
Action to be taken if the patient is excluded	• Refer for fitting of an emergency cu-IUD if patient wishes • Consider Levonorgestrel via PGD • For other exclusions, refer to medical staff or clinic doctor • If excluded because woman is taking liver enzyme inducers, offer referral for Cu-IUD or consider levonorgestrel as a double dose as per Levonorgestrel PGD. • Document advice given
Action to be taken if the patient or carer declines treatment	As above
Cautions	• Proton Pump inhibitors, Antacids and H2 Receptor Antagonist - reduces efficacy, concomitant use not recommended.- suggest Cu-IUD as first choice, if the woman refuses then offer Levonorgestrel (Levonelle®). • Liver Enzyme Inhibitors- ketoconazole, itraconazole, clarithromycin, nefazodone: increase plasma level of Ulipristal acetate (ellaOne®). Clinical relevance unknown. • Hormonal contraception may interfere with the action of Ulipristal. Please refer to advice below • Other progestogen containing products e.g. HRT should not be taken for 5 days following UPA • Additional information to women who are breastfeeding

[1] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

	• The risk to a breastfed child from ingestion of Ulipristal acetate (ellaOne®) is unknown. • Advise to avoid breast feeding for at least 1 week after taking Ulipristal acetate (ellaOne®).

Description of treatment	
Name, strength & formulation of drug	Ulipristal acetate (ellaOne®) 30mg tablet
Legal category	P - Pharmacy only medicine / POM – Prescription only medicine
Black triangle▼	No
Off-label use	This PGD contains "off-label" use in the following circumstances: - Patient with severe hepatic impairment
Route / method of administration	Oral
Dose and frequency of administration	30mg (1 tablet) to be taken as a single dose. Administration while in the pharmacy should be encouraged and supported although this is voluntary. If the Ulipristal acetate (ellaOne®) is not being administered while in the pharmacy a labelled single dose box containing 1 tablet should be given to the patient.
Duration of treatment	One tablet as a stat dose A repeat supply of UPA-EC in the same cycle can be given if clinically indicated. Perform a pregnancy test if period is late or it is two weeks since previous supply to ensure conception has not occurred.
Quantity to be supplied	One tablet
Drug interactions	See section on cautions for details of relevant drug interactions
Identification & management of adverse reactions	Gastro-intestinal disturbances (including nausea, vomiting, diarrhoea and abdominal pain); dizziness, fatigue, headache, menstrual irregularities, back pain, mood changes, breast tenderness and muscle spasms. A detailed list of adverse reactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of	Any adverse reaction to the product should be documented in the

adverse reactions	medical records – inform GP if this is in the best interests of the patient Alert a doctor in the event of serious adverse reaction – call 999 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
Written information to be given to patient or carer	Written Information to be provided:- • Product specific Patient Information leaflet • Contraception & Sexual Health Service Information on taking emergency contraception • A leaflet on all contraceptive methods • A leaflet about sexually transmitted diseases and genito-urinary services (if appropriate)
Patient advice /follow up treatment	Explanation of • Why an emergency IUD is advised instead of other methods. • Mode of action of medication – thought to delay ovulation • Efficacy/failure rate. May be less effective if weight >85kg or BMI > 30 • Emergency contraception administered after ovulation is ineffective • Possible side effects • Action to take if vomiting occurs • Emergency contraception only gives protection for the current risk • Discussion of ongoing contraception – pharmacists should advise patients to attend GP or family planning clinic if they do not have a routine form of contraception • To return for pregnancy test if next menstrual period is lighter, shorter or more than 7 days late • To seek medical advice if low abdominal pain occurs • To take as soon as possible to improve efficacy • To return if any concerns arise • Offer condoms • Refer for STI screening, if appropriate If quick-starting hormonal contraception post ulipristal acetate alternative contraceptive methods should be used alongside hormonal methods for a number of days, as listed below:

UPA = day 0	Methods (day UPA + 5)	Requirement for additional contraception
UPA then wait at least 5 days	Combined oral contraceptive pill (except Qlaira)	7 days
	Qlaira combined oral contraceptive pill	9 days
	Combined vaginal ring/transdermal patch	7 days
	Progestogen-only pill (traditional/desogestrel)	2 days
	Progestogen-only implant or injectable	7 days

https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/

A verbal warning should be given that the tablets may cause nausea and vomiting. If vomiting occurs within three hours of taking the tablets, further advice must be sought immediately.

Give contact telephone number – contraceptive services, or GP, A&E or out of hours service if outside of clinic hours

If symptoms of Pelvic Inflammatory Disease (abdominal pain, pain/discomfort during sexual intercourse, pain on urination, heavy/painful periods, bleeding between periods/after sexual intercourse, unusual vaginal discharge), refer patient to a doctor

Records

Complete record of consultation for emergency contraception which includes;

- Patients name, date of birth, postcode and consent given
- Reason for requesting emergency contraception
- Previous use of EC
- Estimated day of ovulation
- Day in cycle of UPSI
- Time since first UPSI (within 72 hours/within five days/within five days of ovulation)
- Relevant medical history
- LMP normal/abnormal (pregnancy test if indicated)
- Recent menstrual cycle any symptoms described by the patient
- Weight and BMI
- Risk of STI and referral to GUM (if indicated)
- Dose and form administered/supplied
- Batch number and expiry date details
- Advice given to patient (including side effects)
- Signature of Pharmacist
- Signature of patient
- Medication the client is taking which will influence EHC provision
- Referral arrangements (including self-care)

	Input data onto PharmOutcomes.

Characteristics of staff	
Qualifications and professional registration	Registered with the General Pharmaceutical Council

Additional requirements	• Must undertake initial training prior to using the PGD
	• Pharmacists will have
	  ○ Successfully completed CPPE training on Emergency Hormonal Contraception
	  ○ Completed the CPPE Declaration of Competence
	  ○ Appropriate indemnity insurance
	  ○ Systems to protect confidential information
	  ○ awareness of and understanding of the emergency contraception guidelines
	• Must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it
	• Must have undertaken appropriate training for working under PGDs for supply/administration of medicines
	• Must be competent in the use of PGDs for health professionals using patient group directions.
	• Must be familiar with the product and alert to changes in the Summary of Product Characteristics
	• Have access to the Patient Group Direction and associated online resources.
	THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Continued training requirements	• Maintain knowledge and expertise and keep up to date with any changes in the use of EC • Complete refresher e-learning as appropriate in line with the Declaration of Competence

Information sources	
Key references	• Summary of Product Characteristics www.medicines.org.uk • British National Formulary (BNF) https://www.medicinescomplete.com/mc/bnf/current/ • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. Emergency Contraception http://www.fsrh.org • Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. Drug Interactions with Hormonal Contraception. http://www.fsrh.org • London Contraception and Sexual Health PGD Template “PGD for

	the Supply of Ulipristal Acetate 30mg Emergency Contraception by Community Pharmacists" available at https://www.sps.nhs.uk/articles/contraception-and-sti-community-pharmacy-pgd-templates-london/

History of previous versions	
Version:	Significant changes:
02	Update with UKMEC 2016 guidance and FSRH Emergency Contraception 2017 guidance

PGD authorisation and approval		
Developed by:	**Name**	**Date**
Pharmacist	Amy Cantlay	18/07/2017
Doctor	Dr Babiker Elawad	20/07/2017
Registered nurse	Dr Helen McIlveen	20/07/2017
North of Tyne Local Pharmaceutical Committee	Ann Gunning	18/07/2017
Authorised by:	**Name**	**Date**
Interim Deputy Director of Nursing	Elaine Henderson	06/09/2017
Medical Director	Jeremy Rushmer	06/09/2017
Chief Pharmacist / Director of Pharmacy	David Campbell	17/08/2017

Approved for use in Northumbria Healthcare NHS Foundation Trust by the Medicine Management Committee (MMC) on behalf of the Trust wide Assurance Committee		
Authorised by:	**Name**	**Date**
Chairman of MMC	David Campbell	06/09/2017

Authorised for use within the following areas within Northumbria Healthcare NHS Foundation Trust	
Clinical Area	**Matron or Clinical lead for area**
Community Pharmacy	Helen McIlveen

Please see the next page for practitioner signoff. Each practitioner within these areas that is assessed as competent to use this PGD is required to be signed off by their line manager or

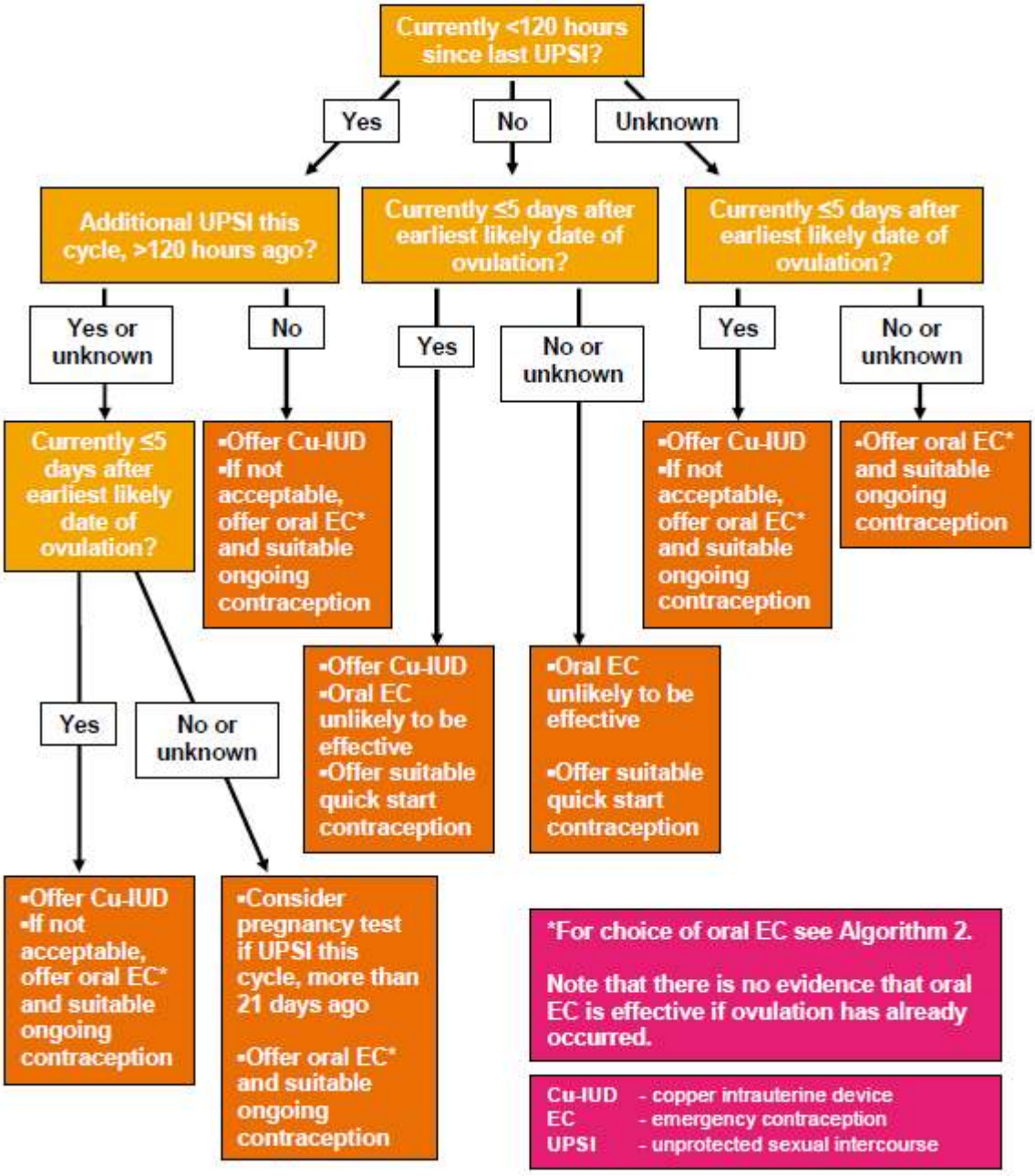
contractor. A copy of this signoff should be retained by the individual and stored within the PGD file maintained by the manager.

Appendix 1

FSRH

Decision-making Algorithms for Emergency Contraception

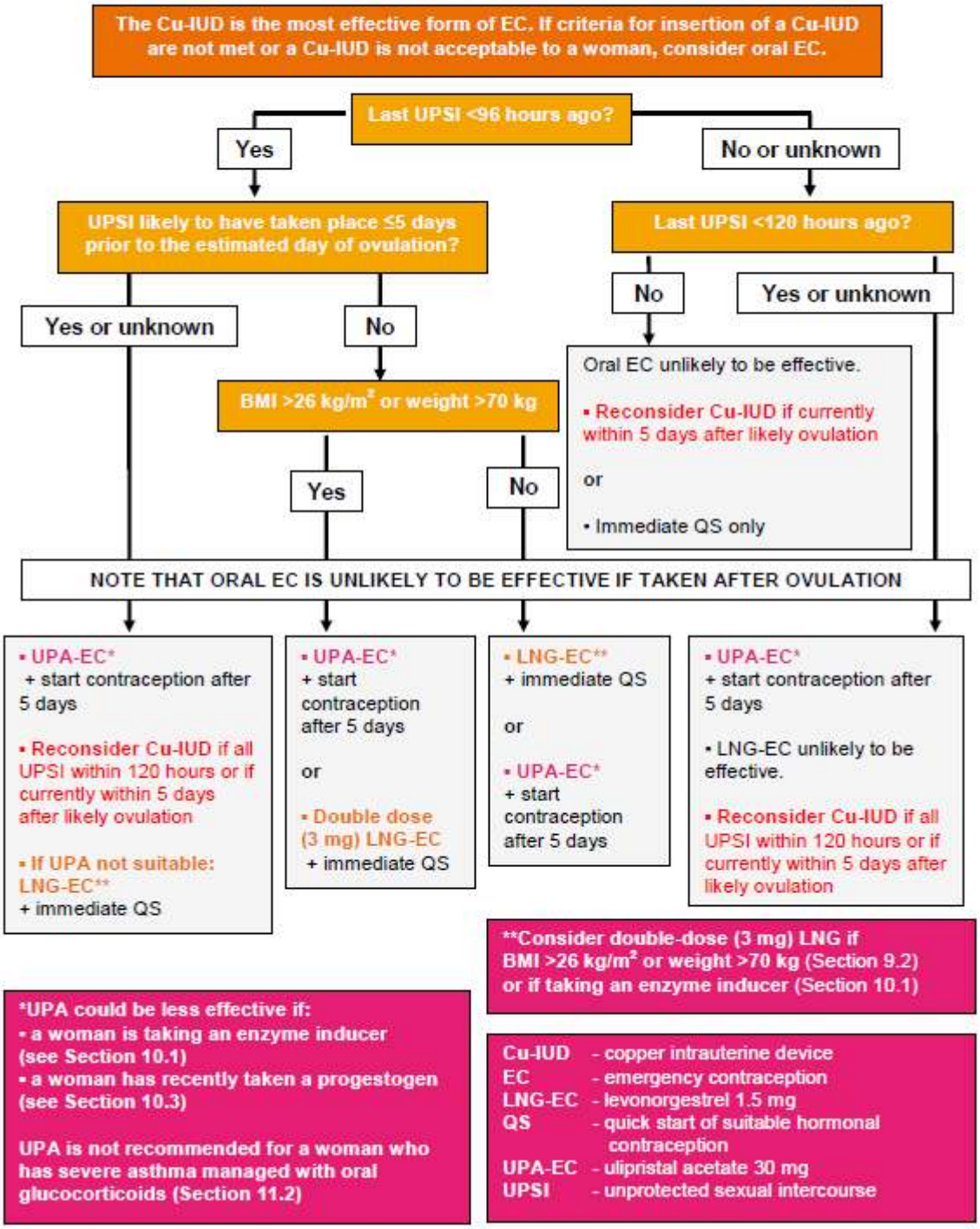
Algorithm 1: Decision-making Algorithm for Emergency Contraception (EC): Copper Intrauterine Device (Cu-IUD) vs Oral EC



Appendix 2

FSRH

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



Northumbria Healthcare NHS Foundation Trust Patient Group Direction for the administration or Supply of **ULIPRISTAL ACETATE (EllaOne®) as Emergency Hormonal Contraception by Community Pharmacists**	PGD: CP02 Version: 02 Issue Date: 6th Sept 2017 Expiry Date: 31st Aug 2020

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE. YOU CANNOT DELEGATE TASKS UNDER THIS PGD TO ANYONE ELSE

IF THIS IS AN UPDATED OR REPLACEMENT PGD 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

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 AUTHORISATION SHEET 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.

Name of Professional	Signature	Authorising Manager's Name	Signature	Date