Northumbria Healthcare NHS Foundation Trust Patient Group Direction for the administration or Supply of **Levonorgestrel 1500micrograms as Emergency Hormonal Contraception by Community Pharmacists**	PGD: CP-01 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 provided at the time of referral in case the IUCD cannot be inserted or the woman changes her mind Ulipristal Acetate (UPA) is generally more effective than levonorgestrel (LNG). However LNG may be preferred if - UPA contraindicated - Has taken progestogens in the week prior to EC - Risk of further UPSI within 5 days as this allows quick starting of hormonal contraceptives
Criteria for inclusion	• Any female in her reproductive years (minimum age 13 years) • Emergency contraception up to 96 hrs after unprotected sexual intercourse (UPSI) that cycle including (but not limited to): o Penetration without ejaculation or ejaculation on external genitals o Barrier method failure – cap or condom o Missed pills without alternative methods used – check missed pill guidelines o Medroxyprogesterone acetate injection overdue by two weeks (i.e. more than 14 weeks since last injection) o Potential intrauterine contraceptive device (IUD) failure, e.g. lost threads o Withdrawal method used o No method used o Following rape or sexual assault o Patients on COC, POP or progesterone implant who are taking enzyme inducers and fail to use additional contraceptive methods. o Intrauterine contraception removed after recent intercourse o Progestogen-only implant or LNG-IUS has exceeded duration of use • 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 • Patient has received progestogen only emergency contraception (EC) but has vomited within THREE hours - offer a repeat dose of Levonorgestrel 1500micrograms, provided she is still within 96 hours of UPSI. • Fraser competent if under 16. • Patient who may not need EC on medical grounds on the basis of failed contraception but show extreme anxiety about conceiving. Levonorgestrel 1500mcg may be considered between 72-96 hours after UPSI, but women should be informed of limited evidence of efficacy, that such use is outside the produce licence, and a more effective alternative is a Cu-IUD or Ullipristal.
Criteria for exclusion[1]	• Known allergy to the active ingredient levonorgestrel or any excipients • Under 13 years • Patient has previously experienced any severe clinical problems with hormonal contraception • Unexplained vaginal bleeding • Hereditory galactose intolerance • Acute porphyria • Individuals under 16 years of age and not competent using the Fraser guidelines unless appropriate adult can consent for them • Patient requests to see a doctor • Pregnancy (where pregnancy is suspected, a pregnancy test should be performed). • Patients refusing treatment under this patient group direction • Patient is not competent to give consent under the Mental Capacity Act • Third party requests • Lactose intolerance • Within 5 days after taking UPA-EC • More than 96 hours after UPSI
Action to be taken if the patient is excluded	• Refer for fitting of an emergency cu-IUD if patient wishes • Consider the use of ullipristal • For other exclusions, refer to GP or sexual health clinic • Document advice given
Action to be taken if the patient or carer declines treatment	• As above
Cautions	• A history of active or poorly controlled intestinal malabsorption disease, e.g. Crohn's Disease because this may impair the efficacy of Levonorgestel. Absorption may also be affected by gastric bypass surgery. • The effectiveness of levonorgesterel is reduced in women taking liver enzyme inducing drugs (and possibly for 4 weeks after stopping); a copper intra-uterine device should be offered instead

[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

	or the dose of levonorgesterel should be increased to a total of 3mg taken as a single dose within 96 hours of UPSI. Enzyme inducing drugs include: barbiturates, primidone, phenytoin, carbamazepine, phenylbutazone, St John's Wort, rifbutin, griseofulvin, rifampicin or ritonavir. See BNF for full list of affected drugs. • Ciclosporin metabolism is inhibited by progestogens (increase plasma concentration). Women who are taking ciclosporin may wish to consider use of non-hormonal methods of contraception such as IUD, but hormonal methods could be considered after consultation with the patients consultant (FFPRHC 01/09/06) • Note- commonly used antibiotics do not interfere with EC. There is no need to increase the dose for emergency contraception if the patient is taking antibacterial's that are not enzyme inducers. • If there are symptoms of Pelvic Inflammatory Disease - Refer to a doctor • Levonorgestrel is considered to be less effective if patient weighs > 70kg or BMI >26. Cu-IUD or UPA should be used unless contraindicated. If other options contra-indicated/declined may use a double dose of 3mg LNG. • Up to 5 days prior to estimated ovulation date, or date of ovulation unknown – UPA more effective in these situations

Description of treatment	
Name, strength & formulation of drug	Levonorgestrel 1500mcg tablets
Legal category	POM - Prescription only medicine / P – Pharmacy only medicine
Black triangle▼	No
Off-label use	This PGD contains off-license use in the following situations, in accordance with guidance from FSRH: - Double dose if taking an enzyme inducer or has finished a course of an enzyme inducer in the last month - Double dose if weight over 70kg or BMI over 26 - Use between 72 – 96 hours - Use in individuals with previous salpingitis or ectopic pregnancy - Use in patients with severe hepatic impairment
Route / method of administration	Oral
Dose and frequency of administration	1500microg (1 tablet) to be taken as a single dose as soon as possible after UPSI A dose of two tablets taken together should be used if the patient is taking a liver enzyme inducing drug, or has finished a course of an enzyme inducer in the last month. A douible dose may also be used if the patient weighs more than 70kg or has a BMI over 26kg/m2. Administration while in the pharmacy should be encouraged and

	supported although this is voluntary. If the levonorgestrel is not being administered while in the pharmacy a labelled single dose should be given to the patient.
Duration of treatment	One stat dose A repeat supply of Levonorgestrel 1500micrograms 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 of Levonorgestrel 1500mcg to ensure conception has not occurred. A second course is not required if UPSI occurs within 12 hours of taking the first course of Levonorgestrel 1500micrograms.
Quantity to be supplied	One tablet Two tablets if the patient is taking a liver enzyme inducing drug or had finished a course of an enzyme inducer in the last month or weighs over 70kg or BMI over 26.
Drug interactions	See section on cautions for details of relevant drug interactions and current edition of British National Formulary
Identification & management of adverse reactions	Nausea and vomiting both reduced by taking after a light meal Breast tenderness, low abdominal pain, headaches, dizziness and fatigue Bleeding patterns may be temporarily disturbed 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 adverse reactions	Any adverse reaction to the product should be documented in the 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	Give following information leaflets: • 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 infections 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 – thought to inhibit or delay ovulation • Efficacy/failure rate - varies depending upon when in the cycle

	UPSI has occurred. The failure rate increases with time and increased weight. Emergency contraception taken 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 sexual health 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 Patients who present having missed one or more of their oral combined contraceptive tablets should be advised to continue taking their normal oral contraceptive for the remainder of the cycle. They should also be advised to use barrier methods of contraception for the next seven days (2 days for POP, 9 days for Qlaira). If these seven days run into a pill free interval (or placebo tablets of an ED pack), patients should be advised to omit the pill free interval (or placebo tablets) and start the next pack of pills immediately 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. Additional information to women who are breastfeeding • Very small amounts of levonorgestrel may appear in breast milk. This is not enough to be harmful to the baby but if patients are concerned, tablets should be taken immediately after a breast feed to minimise the active ingredient in the next feed. Give a contact telephone number – contraceptive services, GP, A&E or Out of Hours services. 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 • Risk of STI and referral to GUM (if indicated) • Weight and BMI • Dose and form administered/supplied • Batch 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 training
	  ○ Completed the CPPE Declaration of Competence
	  ○ Appropriate indemnity insurance
	  ○ Systems to protect confidential information
	  ○ Awareness and understanding of the emergency contraception guidelines including advanced supply of levonorgestrel
	• 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 Group Template. "Patient Group Direction for the Supply of Levonorgestrel 1.5mg Emergency Contraception by Community Pharmacists" Available via 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

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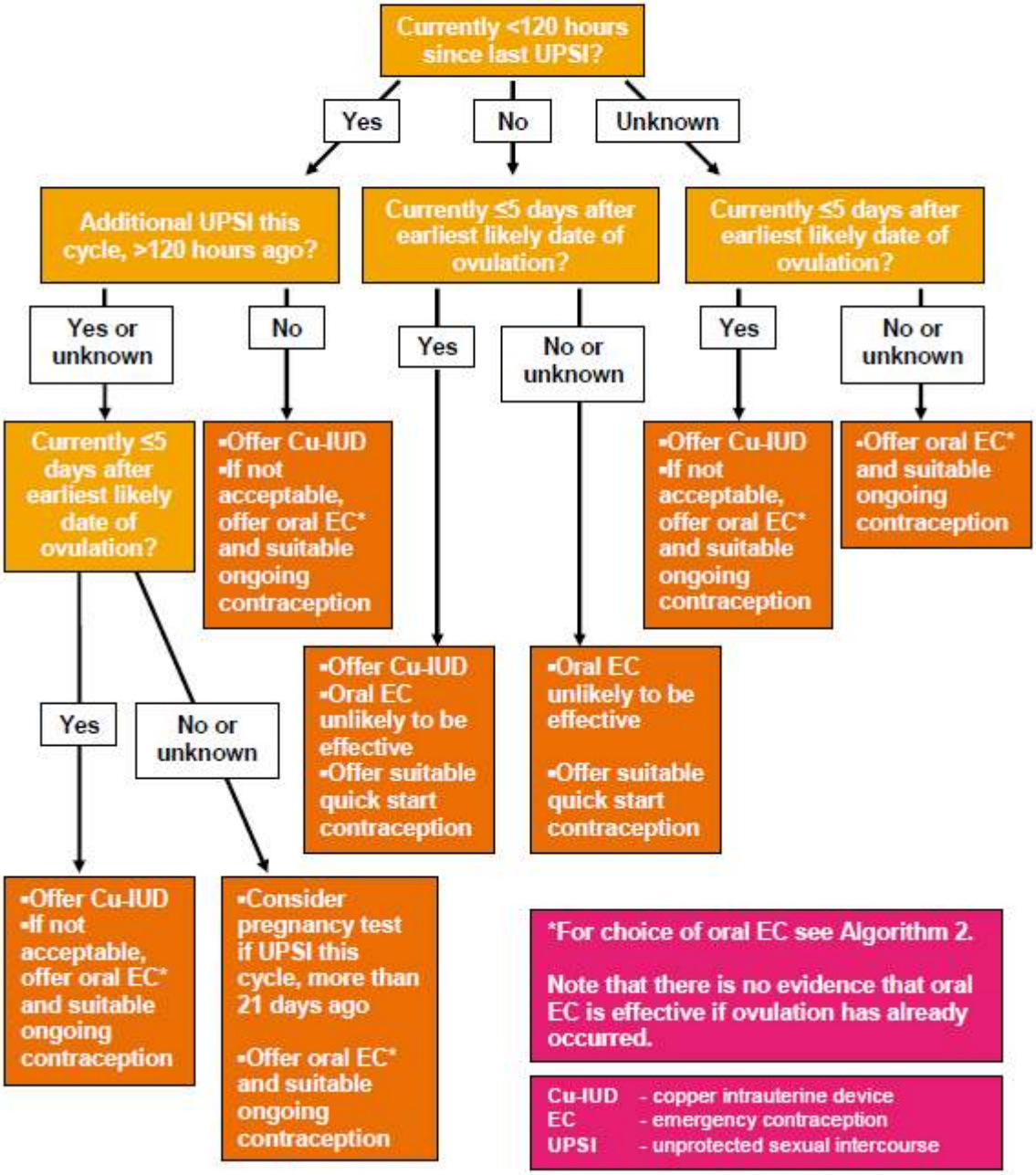
Decision-making Algorithms for Emergency Contraception

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



Appendix 2

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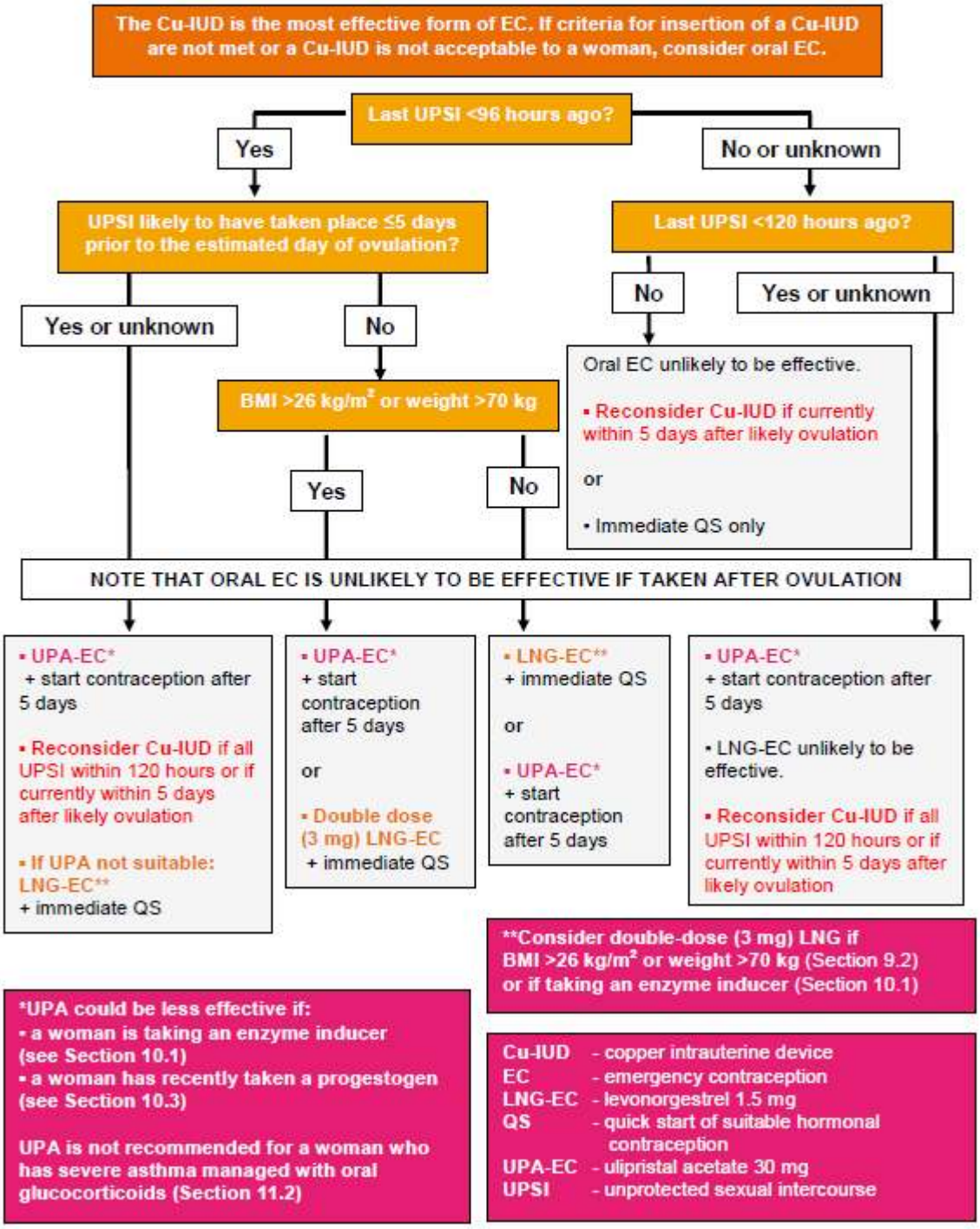
Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)



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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