Bath & North East Somerset Council

# PATIENT GROUP DIRECTION (PGD) FOR LEVONORGESTREL TABLET SUPPLIED AS LEVONELLE 1500

## Section 1
## CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR LEVONORGESTREL TABLET SUPPLIED AS LEVONELLE 1500

**YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT**

| | |
|---|---|
| **Organisation and service** | |
| **Bath & North East Somerset Council** | ▪ Community Pharmacists providing an emergency contraception service under the Sexual Health enhanced service contract commissioned by B&NES Council<br>▪ Primary Care (BANES CCG) |
| **Period** | |
| **Date PGD comes into effect** | 1st May 2018 |
| **Expiry date** | 30th April 2020 |
| **Staff characteristics** | |
| **Professional qualifications** | Registered Pharmacists who have received training to undertake administration and supply of medicines under Patient Group Directions and are competent in the management of contraception care, working in a community pharmacy under the Sexual Health enhanced contract |
| **Specialist competencies or qualifications** | Must fit all the following criteria:<br>▪ have undertaken appropriate training for working under patient group directions for the supply and administration of medicines<br>▪ have been assessed as competent to work with this PGD<br>▪ have undertaken training in the role, care and administration of the medicine specified in this PGD<br>▪ have access to the current BNF (https://www.medicinescomplete.com/mc/bnf/current) |
| **Continuing training and education** | The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development |
| **Clinical Details** | |
| **Indication** | Emergency contraception for females within 72 hours following unprotected sexual intercourse (UPSI) or contraceptive failure. |

| | |
|---|---|
| **Inclusion criteria** | Patients aged 13 years and over at risk of unwanted pregnancy if presenting to pharmacists who are agreed participants in the Sexual Health enhanced service contract<br><br>1. Emergency contraception is indicated and levonorgestrel is an appropriate choice of emergency contraception[2] (see appendices 1 and 2 and FSRH guideline – Emergency contraception)<br>2. Have been advised about the effectiveness of intrauterine (IUCD) methods and oral methods of emergency contraception and have chosen the oral method[3] (see appendices 1 and 2 and FSRH guideline – Emergency contraception)<br>3. Have provided valid consent to treatment with levonorgestrel<br><br>**and** also fulfil one of the following 4 criteria:<br><br>1. UPSI with previous 72 hours (see appendix 2 and FSRH guideline – Emergency contraception)<br>*2.* UPSI within previous 73 to 96 hours[4] (see appendix 2 and FSRH guideline – Emergency contraception) and Ulipristal is contra-indicated or not suitable.<br>3. Have vomited within 2 hours of ingestion of a 1st supply (as 1 or 2 above) of levonorgestrel 1500mcg but still within 72/96 hours of unprotected sexual intercourse. NB: option of IUCD should be offered again if appropriate<br><br>4. Are unduly worried even though the EHC is not warranted (see FSRH guideline – Emergency contraception)<br><br>• **If the client is under 16:** discuss the value of parental support and encourage client to inform parent(s). An assessment of the Fraser Guidelines on Competency must be made:<br><br>  • Mature enough to understand the advice and implications<br>  • Cannot be persuaded to discuss with parents<br>  • Likely to have had or continue to have sexual intercourse<br>  • Physical or mental health likely to suffer if does not receive contraceptive help<br>  • In the client's best interest to receive contraception without parental consent. |

| | |
|---|---|
| | Any patient under the age of 16 must be deemed to be Fraser competent and safeguarding guidelines must be followed. |
| **Exclusion criteria** | ▪ Patients aged 25 and over<br>▪ No valid consent<br>▪ Unprotected intercourse more than 72 hours earlier in the same menstrual cycle (for these patients consider IUCD insertion or Ulipristal) - refer the patient to their GP or sexual health service.<br>▪ Pregnancy or suspected pregnancy (advise patient of need to test to exclude pregnancy)<br>▪ Hypersensitivity to levonorgestrel or any constituent of Levonelle 1500 (see patient information leaflet)<br>▪ Severe hepatic dysfunction<br>▪ Active acute porphyria<br>▪ Severe malabsorption syndromes (e.g. Crohn's disease)<br>▪ Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption<br>▪ Lack of capacity to consent or unable to assess competency of women less than 16 years<br>▪ Patients under 13 years<br>▪ Drug interactions (see below). NB current use or use within the previous 28 days of enzyme-inducing drugs are an exclusion for this PGD and patients should be referred to their GP or the sexual health service<br>▪ Requests from third parties<br>▪ Patient has had UPSI immediately prior to predicted date of ovulation and therefore has been advised that Ulipristal would be a more appropriate choice of oral emergency contraception. Please refer to FSRH Emergency Contraception March 2017, updated December 2017; section 7.2, page 10) |
| **Action if patient declines or is excluded** | Document refusal and action taken in the patient record.<br><br>Refer to GP or sexual health service. Consideration should be made for alternative EHC or IUCD insertion as per current guidance. |

| | |
|---|---|
| **Circumstances under which further advice should be sought from a doctor and arrangements for referral** | ▪ Request for EHC at or about 72 hours since UPSI (for GP/ community pharmacy)<br>▪ Regular attendees<br><br>**Patients weighing >70kg and / or BMI > 26kg/m$^2$:**<br>Recommended that Ulipristal (UPA-EC) is offered if a Cu-IUD is not indicated or not acceptable, or in addition to a Cu-ID. If UPA-EC is not suitable, a double dose (3 mg) of LNG-EC can be used.<br><br>**Patients weighing >85 kg or with a BMI >30 kg/m$^2$:**<br>3 mg LNG-EC (or UPA-EC) can be offered (no evidence of one being more effective than the other).<br><br>Refer to GP or sexual health service. Consideration should be made for alternative EHC or IUCD insertion as per current guidance.<br><br>If under 13 years old, follow local safeguarding policy.<br><br>Patients presenting to a pharmacy following rape or sexual assault can be prescribed emergency hormonal contraception but should be referred to the Sexual Assault Referral Centre (SARC) and encouraged to inform the Police.<br><br>SARC contact details:<br>0117 342 6999<br>ubh-tr.thebridgecanhelp@nhs.net<br>https://www.thebridgecanhelp.org.uk/ |
| **Drug Details** | |
| **Name, form & strength of medicine** | Levonorgestrel 1.5 mg tablet supplied as Levonelle 1500 |
| **Legal Status/classification of medicine** | Prescription only medicine |
| **Route/method of administration** | Oral – stat dose taken on premises. To be swallowed whole, not chewed, with water |

| | |
|---|---|
| **Dosage** | ▪ 1 x 1.5 mg levonorgestrel tablet to be taken as soon as possible, preferably within 12 hours, and no later than 72 hours after unprotected sexual intercourse<br>▪ If vomiting occurs within 3 hours of taking the tablet, another tablet should be obtained and taken as soon as possible<br>▪ Levonorgestrel must be taken as supervised consumption on the premises. |
| **Frequency** | Single dose within menstrual cycle unless vomited within 3 hours of taking the first tablet. It can be taken at any point during the menstrual cycle unless menstrual bleeding is overdue |
| **Duration of treatment** | Single dose |
| **Maximum or minimum treatment period** | One 1.5 mg tablet taken as a single dose |
| **Quantity to supply/administer** | 1 x 1.5 mg levonorgestrel tablet as original pack |
| **Storage** | Store in original container in order to protect from light |
| **Cautions** | ▪ Risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy) – Use with caution<br>SPC states: "*Levonelle 1500 is not recommended for patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy).*" However FSRH guidance states: "…*emergency contraceptives containing LNG-EC …do not increase the chance that a pregnancy will be ectopic. Moreover, in common with all contraceptive methods, EHC reduces the absolute risk of ectopic pregnancy by preventing pregnancy in general. A previous ectopic pregnancy is not a contraindication to use*."<br>▪ Breast-feeding women - advise to take EHC immediately after a feed<br>▪ Limited and inconclusive data suggest that there may be reduced efficacy of Levonelle 1500 with increasing body weight or body mass index (BMI). In all women, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of the woman's body weight or BMI |
| **Interactions** | The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers.<br><br>Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include: |

| | |
|---|---|
| | ▪ barbiturates (including primidone)<br>▪ phenytoin<br>▪ carbamazepine<br>▪ herbal medicines containing Hypericum perforatum (St. John's Wort)<br>▪ rifampicin<br>▪ ritonavir<br>▪ rifabutin<br>▪ griseofulvin<br><br>Women taking such drugs should be referred to their GP for advice.<br>Medicines containing levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism. Women taking cyclosporin containing medication should be referred to their GP for advice.<br><br>See British National Formulary (BNF) or Summary of Product Characteristics (SPC) (available at https://www.medicinescomplete.com/mc/bnf/current or www.medicines.org.uk) for full details as this list is not exhaustive. |
| **Side effects** | ▪ nausea<br>▪ vomiting – if vomiting occurs within 3 hours of taking the progestogen only emergency contraceptive a further dose should be given<br>▪ breast tenderness<br>▪ headaches<br>▪ lower abdominal pain<br>▪ dizziness<br>▪ diarrhoea<br>▪ fatigue<br>▪ Menstrual irregularities<br><br>Women should be provided with written information on how to access help and advice should any side effects occur<br><br>NB: This is not a full list of side effects. It is a summary of those that are common, clinically significant or severe.<br>See British National Formulary (BNF) or Summary of Product Characteristics (SPC) (available at https://www.medicinescomplete.com/mc/bnf/current or http://www.medicines.org.uk) for full details of adverse effects. |

| | |
|---|---|
| | **Suspected Adverse Reactions**<br>If an adverse reaction is suspected this should be reported to the Medicines Healthcare products Regulatory Agency (MHRA) through the Yellow card reporting scheme, which can be found in the back of the BNF or on the web site: http://www.mhra.gov.uk or www.yellowcard.gov.uk<br><br>*Any adverse reaction associated with the use of this PGD, which is reported through the Yellow Card System, should additionally be reported via the organisations adverse incident reporting system.* |
| **Advice to Patient** | ▪ Use medication as an emergency measure<br>▪ All eligible women should be offered the Cu-IUD (available from the GP or sexual health service) as it is considered the most effective method of emergency contraception due to the low documented failure rate.<br>▪ Advise patients on options of long term methods of contraception. Emphasise that these tablets are for emergency use only as they are not effective for regular contraception.<br>▪ Emergency contraceptive methods are not abortifacient and this should be emphasised when counselling prior to use.<br>▪ Use of emergency contraception does not replace the necessary precautions against sexually transmitted infection<br>▪ Advise patient that she could still become pregnant.<br>▪ Inform the patient that their next period may be early, on time or late; and to refrain from intercourse or use an additional barrier method of contraception until after next bleed. If the next menstrual period is more than 5 days overdue, or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded.<br>▪ If vomiting occurs within 3 hours of taking the progestogen only emergency contraceptive a further dose should be obtained.<br>▪ Seek medical advice if there is any lower abdominal pain.<br>▪ If a pregnancy has occurred, following levonorgestrel treatment, the patient should contact GP for follow-up to ensure that it is not ectopic.<br>▪ Missed or late oral contraceptive tablets – inform the patient that treatment with Levonelle 1500 is in addition to that day's normal tablet. Following use of Levonelle, additional precautions (condoms or refraining from sex) |

| | |
|---|---|
| **Advice to Patient** continued | should be advised for 7 days when continuing combined hormonal contraceptives, 2 days for progestogen only pill and 9 days for Qlaira<br>▪ Patients should be signposted to sexual health service or GP to access condoms and ongoing contraception<br>▪ If under 16 years old she should be encouraged to inform a guardian or responsible adult.<br>▪ The available evidence suggests that pregnancies occurring after levonorgestrel failure are not associated with any major congenital malformations, pregnancy complications or other adverse pregnancy outcomes<br>▪ The Patient Information Leaflet (PIL) should be provided |
| **Follow up actions** | ▪ If unprotected sexual intercourse took place more than 72 hours ago advise patient to seek urgent medical advice and refer immediately to sexual health service or GP.<br>▪ Advise patient to attend the GP or sexual health service regarding future contraception. If the next period is absent or abnormal, she should consider the possibility of pregnancy and be advised how to obtain a test. |
| **Audit trail** | |
| **Records/audit trail** | Associated local documentation for the issue of EHC in line with the enhanced service contract must be used.<br><br>You must record:<br>▪ Reason for emergency hormonal contraception (EHC)<br>▪ Date and time of unprotected sexual intercourse (UPSI)<br>▪ Previous use of EHC<br>▪ Date of last menstrual period (LMP) stage of cycle when UPSI occurred<br>▪ Any contraindications to Levonelle 1500<br>▪ Current medication, diarrhoea and vomiting<br>▪ Discussions with the patient about ongoing contraception and referral for STI screening at GP or sexual health service as necessary<br>▪ Follow up discussed<br><br>As per all PGDs also record:<br>▪ Date<br>▪ Patient's name, address, date of birth and consent given by patient/parent/guardian<br>▪ Contact details of GP (if registered)<br>▪ Indication for use<br>▪ Brand name if applicable<br>▪ Dose administered (if applicable)<br>▪ Route |

| | |
|---|---|
| | ▪ Batch number<br>▪ Expiry date<br>▪ Date of administration<br>▪ Patient information leaflet(s) offered<br>▪ Advice given to patient/parent/guardian (including side effects)<br>▪ Referral arrangements (including self-care)<br>▪ Name and designation of healthcare professional who administered or supplied the medication.<br>▪ Details of any adverse drug reaction and actions taken including documentation in the patient's medical record<br>▪ Any additional advice sought from a doctor or other health care professional |

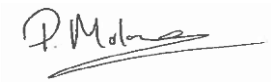
## References used for this PGD

**This PGD is based on the Levonorgestrel PGD developed by Virgin Care March 2018, and was drawn up in consultation with:**

| Name | Speciality |
|---|---|
| Paul Moloney | Lead Pharmacist, Virgin Care B&NES |
| Dr Arnold Fernandes | Consultant in Genitourinary Medicine and Contraception, The Riverside Clinic, Royal United Hospital NHS Foundation Trust |
| Jayne Elton | Lead Nurse Practitioner, The Riverside Clinic, Royal United Hospital NHS Foundation Trust |
| Claire Hookway | Pharmacist, Boots The Chemist Southgate, Bath |
| Paul Sheehan | Public Health Commissioning and Development Manager, Bath and North East Somerset Council |

## Section 2
MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR
**LEVONORGESTREL TABLET**
**SUPPLIED AS LEVONELLE 1500**

This patient group direction must be agreed to and signed by all health care professionals involved in its writing and who use it. The Authorising Organisations lead should hold the original signed copy. The PGD must be easily accessible in the clinical setting

| **Authorisation** | |
|---|---|
| **Specialist Medical Clinician:**<br>**Dr. Arnold Fernandes** | Name: DR. ARNOLD FERNANDES<br>Signature:  Date: 25th April 2018<br>Job title: Consultant in Genitourinary Medicine and Contraception,The Riverside Clinic, Royal United Hospital NHS Foundation Trust |
| **Lead Pharmacist:**<br>**Paul Moloney** | Name: PAUL MOLONEY<br>Signature:  Date: 25th April 2018<br>Job title: Lead Pharmacist, Virgin Care B&NES |
| **Organisational Authorisation:**<br>**Dr. Bruce Laurence** | Name: DR. BRUCE LAURENCE<br>Signature:  Date: 25th April 2018<br>Job title: Director of Public Health, B&NES Council |

## Individual Authorisation

**YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO 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 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 copy of the authorisation sheet showing their authorisation.

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

| Name of Professional | Signature | Authorising Manager | Date |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| **Appendix 1**<br>Self-assessment of competencies for supply of **LEVONORGESTREL TABLET SUPPLIED AS LEVONELLE 1500** under patient under patient group direction | | |
|---|---|---|
| **Name of Professional** | **Location** | **Date** |
| | | |

With reference to

a) PGD for **LEVONORGESTREL TABLETSUPPLIED AS LEVONELLE 1500**
b) Patient Information Leaflet

**and** to be used in conjunction with

c) References contained within the PGD

**Eligibility to Practice**

The Practitioner will:

have a good working knowledge of why **LEVONORGESTREL TABLET SUPPLIED AS LEVONELLE 1500** is recommended

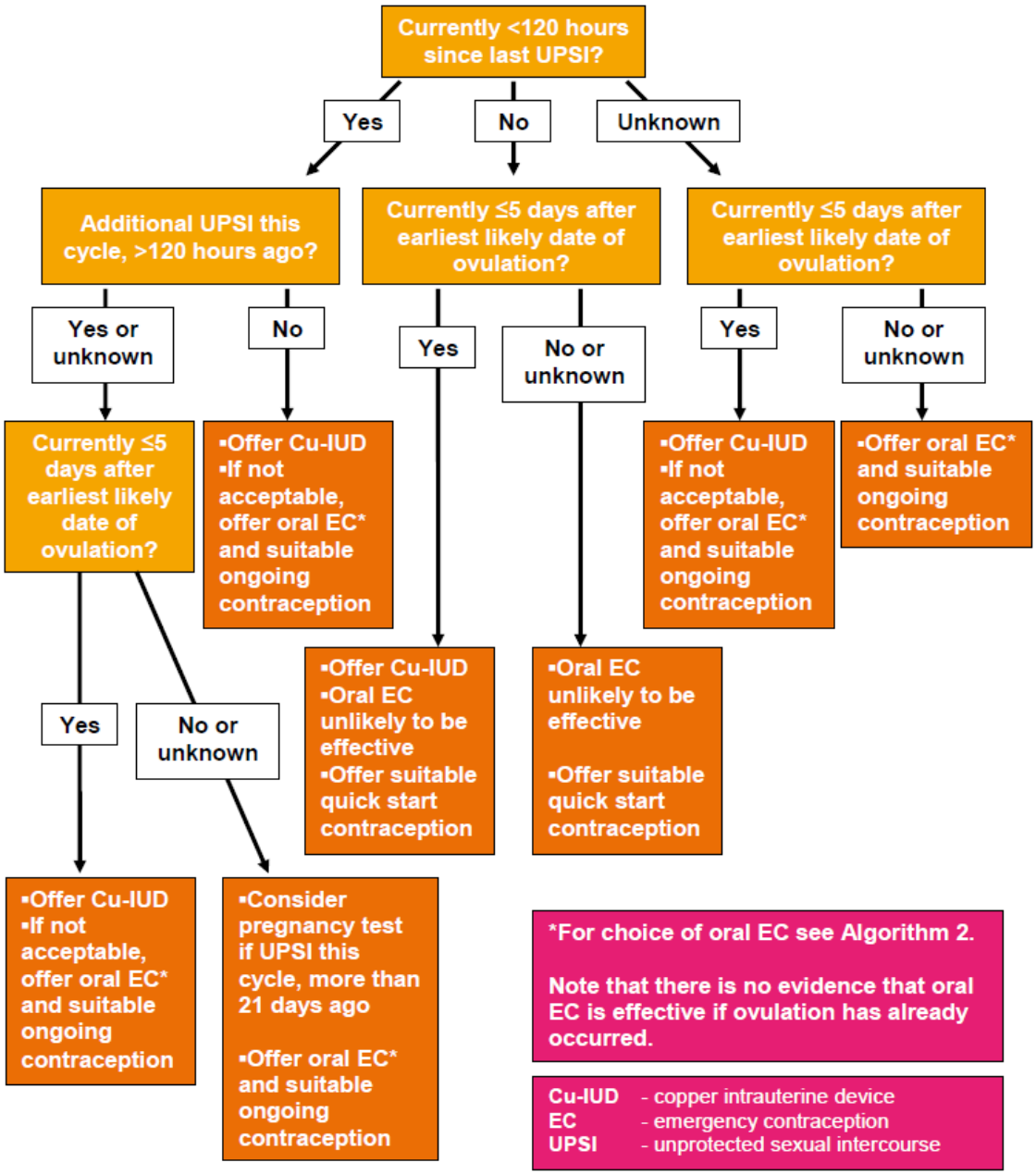
a) have completed my organisations approved training on Patient Group Directions
b) demonstrate the following competencies when administering and supplying the above named medicine

| | **Knowledge** | **Signature & date** |
|---|---|---|
| 1 | Identify local and national policies, Patient Group Direction and procedures used in the administration/supply of the above named medicine | |
| 2 | Describe the mode of action of the above named medicine | |
| 3 | Describe the clinical indications under which the patient is eligible for treatment. | |
| 4 | Describe the contraindications/exclusions to the use of the above named medicine. | |
| 5 | Explain the circumstances under which further advice from the doctor would be sought and arrangements for referral. | |
| 6 | Describe the administration process for the above named medicine including dose and site. | |
| 7 | Describe any possible side effects or interactions of the above named medicine | |
| 8 | Discuss the relevant warnings and patient information to be given. | |
| 9 | Explain the record keeping required in your area of work. | |
| 10 | Undertake Continual Professional Development relevant to the above named medicine and the clinical area to which this PGD relates. Request updates to the PGD when changes to guidance necessitate this. | |

FSRH

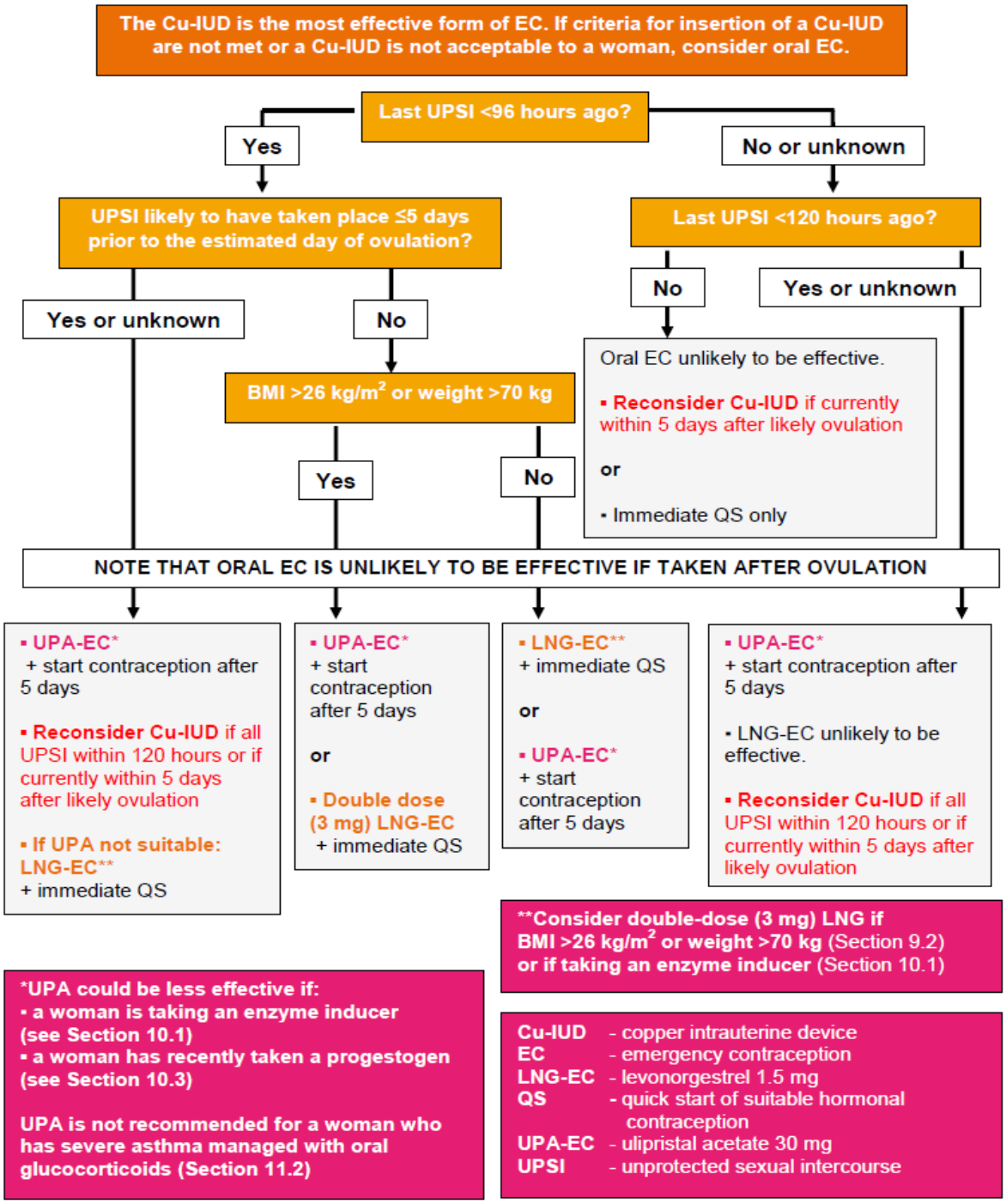
## Decision-making Algorithms for Emergency Contraception

**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)**




x

## Abbreviations used in this Patient Group Direction

| | |
|---|---|
| B&NES | Bath and North East Somerset |
| BMI | Body Mass Index |
| BNF | British National Formulary |
| CCG | Clinical Commissioning Group |
| CSP | Chlamydia Screening Programme |
| Cu-IUD | Copper IntraUterine Debice |
| EHC | Emergency Hormonal Contraception |
| GP | General Practitioner |
| IUCD | IntraUterine Contraceptive Device |
| LNG-EC | Levonorgestrel Emergency Contraception |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| POM | Prescription Only Medicine |
| SARC | Sexual Assault Referral Centre |
| SPC | Summary of Product Characteristics |
| UPA -EC | Ulipristal Emergency Contraception |
| UPSI | UnProtected Sexual Intecourse |