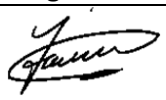
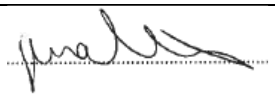
**Patient Group Directions for Supply and Administration of Levonorgestrel 1.5 mg tablet Progestogen-only Emergency Hormonal Contraception (EHC)**
**By**
**Accredited Pharmacist from Community Pharmacies contracted with Population Health Tameside**

**PATIENT GROUP DIRECTIONS**
**FOR THE ADMINISTRATION OF**
**Levonorgestrel 1.5 milligrams (mg)**
**POM (Prescription only medicine)**

These directions are a legal requirement to Pharmacists to supply or administer medication without a prescription. They do not confer prescribing rights. They should be discussed and agreed by both the practice lead pharmacist or manager and each individual pharmacist and then signed by both parties. A copy should be retained in a safe place available at all times.

All professionals hold personal accountability for their actions under the direction and are advised to hold professional indemnity insurance. They are accountable to the doctor responsible for this PGD. Pharmacies are advised to check the pharmacy insurance for vicarious liability. It is also suggested that this additional responsibility be recognised within the job description/contract.

**These directions have been produced and approved by:**

| Name | Designation | Signature | Date signed |
|---|---|---|---|
| Faisal Bokhari | Head of Medicines Optimisation<br>NHS Greater Manchester Integrated Care – Tameside |  | 11 May 2023 |
| Dr Matthew Johnson | Public Health Clinical Lead (Primary Care - Sexual Health)<br>Tameside MBC |  | 11 May 2023 |
| James Mallion | Interim Assistant Director Population Health, Tameside MBC |  | 11 May 2023 |

**Version:** 3.1
**Issue date:** 1 April 2023
**Expiry date:** 31 March 2025

**Patient Group Directions for the Administration of Levonorgestrel 1.5 mg**

**Document Control**

**Document Location**
**Copies of this document can be obtained from**

| | |
|---|---|
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|---|---|
| **Version** | 3.1 |
| **Issued by** | Pamela Watt, Population Health, Tameside MBC |
| **Date** | 16 May 2023 |
| **Review date** | 1 October 2024 |

**Version History**

| Version | Dates | Reason for update |
|---|---|---|
| Version 3.1 | 1 April 2023 to 31 March 2025 | Updated front two pages; text updated with minor amendments |
| Final produced by Victoria Heyes | 9 April 2020, for 6 months; extended to 31 March 2022; extended to 31 March 2023 | Updated with minor amendments |
| Final produced by Richard Scarborough | 1 October 2018 to September 2020 | Variation made due to COVID 19 |

**Patient Group Directions for the Administration of Levonorgestrel 1.5 mg**

**CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR SUPPLY OF** Levonorgestrel 1.5mg

| **Staff characteristics** | |
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| **Qualifications** | • Community pharmacist registered with the General Pharmaceutical Council<br>• Works in a pharmacy contracted to NHS England within Tameside |
| **Additional Requirements** | • Has an understanding of how to use this PGD<br>• Completed competencies and objectives as per the Centre for Pharmacy Postgraduate Education ( CPPE) e learning programme for emergency contraception<br>• If administering EHC to under 16 year olds, has undertaken training in assessing Fraser competency, safeguarding children and young people using CPPE<br>• Must complete the Self-declaration of Competence (DOC) for community pharmacy for emergency contraception with the use of a patient group direction document using CPPE |
| **Continued Training and education Requirements** | • To maintain own level of competency by regular updating and produce evidence of continuing professional development<br>• The pharmacist must maintain a regular self-assessment declaration of competency every 2 years or sooner if appropriate<br>• To maintain competency in local child protection policies/procedures |

| Clinical Details - **Levonorgestrel 1.5mg** | |
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| **Situation to which the PGD applies** | Provision of emergency contraception (EC) by accredited pharmacists to females presenting for oral emergency contraception by community pharmacies in Tameside either in person or remotely in specific circumstances, for example, during pandemics. A remote consultation may be undertaken by telephone, video appointment or via an online assessment.<br><br>This PGD should be used in conjunction with the PGD for Ulipristal Acetate. The decision-making algorithms 1 & 2 and table 1 should be used as an aid in choosing the most appropriate method of EC in individual circumstances. These documents are attached as appendices.[4] |
| **Inclusion criteria** | This service is available to clients who have had unprotected sexual intercourse (UPSI) within the last 72 hours including the potential failures of contraceptive methods and who<br>• are aged 13 years and over<br>• are Fraser competent If under 16 years of age<br>• are deemed competent to consent to treatment,<br>• understand the risks and benefits and that Copper IUD is superior<br>• have no contra indications to progestogen<br>If safeguarding concerns are identified in any client under 18 years referral should be made in line with local policy/procedures.<br><br>**1. Failure of Barrier methods**<br>**2. Failure of Combined oral contraceptive (COC) pill** |

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| | • If pill free interval (PFI) has extended to 9 days or more and UPSI occurred within 7 days of recommencing the pill or in PFI<br>• There is no need to give EC for forgotten pills after 7 pills have been taken, unless more than 7 active pills have been missed in the current packet<br>• COC to be resumed immediately with additional barrier contraception for 7 days (Except for Qlaira additional precautions for 9 days). Next packet should be started without a break if pills missed in last 7 of packet<br>• Client has UPSI /failed barrier method during or in the 7 days after episodes of vomiting or diarrhoea<br>3. **Failure of Contraceptive patch**: If more than 48 hours late applying patch after pill or patch free interval or patch detached for more than 48 hours and UPSI occurred in week 1<br>**4. Failure of Progestogen only pill (POP)**<br>• One or more pills taken more than 3 hours late with Norethisterone/ levonorgestrel or more than 12 hours late with Desogestrel<br>• POP should be continued with addition barrier contraception until 2 pills have been taken continuously<br>• Client has UPSI during or in the 2 days after episodes of vomiting or diarrhoea<br>5. **IUD/IUS**: has expired<br>6. **Depo Provera**: if more than 14 weeks from previous injection, or in the first 7 days after a late injection has been given<br>7. **Progestogen only implants**: indicated if UPSI /failed barrier method in first week of use, if inserted beyond Day 5 of cycle, or implant expired<br>**Post-partum**: UPSI 21 days or more post-delivery (even if breast feeding, unless meets criteria for lactational amenorrhoea)<br>**Post Termination of pregnancy, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease**: UPSI after 5 days or later<br>In all cases IUD should be discussed and referral offered. If the client is within 5 days of UPSI, or 5 days of earliest predicted time of ovulation, an emergency IUD is the treatment of choice, which should be discussed with all clients. If referred on for emergency IUD, Levonorgestrel or Ulipristal Acetate should still be administered if within the confines of the available PGDs.<br><br>Note ovulation can be expected up to day 19 of a 28 day cycle. |
| **Use outside the Terms of the Marketing Authorisation License** | In the following circumstances, Levonorgestrel 1.5 mg may be used outside the terms of the marketing authorisation, as such use is justified by current best practice. If used outside the licensed indication then this must be documented in the consultation record.<br><br>a. Client vomits within 3 hours of taking the tablet a second dose can be issued |

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| | b. Client presents between 72-96 hours after UPSI<br>c. Client on liver enzyme inducers- 3mg to be taken as single dose (refer to concurrent medication) but inform that less reliable and copper coil a better option<br>d. Client has a body mass index (BMI) of >26 kg/$m^2$ or weight >70kg - 3mg to be taken as single dose as soon as possible within 96 hours of UPSI or consider Ulipristral Acetate<br>e. Oral EC can be given more than once in the same cycle. Levonorgestrel EC can be repeated without any restrictions of timing. Levonorgestrel EC should not be given within 5 days of Ulipristal Acetate (see concurrent medication) and Ulipristal Acetate should not be given within 7 days of Levonorgestrel<br>f. Levonorgestrel can be used for a recent episode of UPSI even if there have been earlier episode(s) of UPSI outside the treatment window (>96 hours), as evidence shows that it does not disrupt an existing pregnancy and is not associated with foetal abnormality |
| **Concurrent medication** | If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction refer to Appendix 1 of BNF on www.bnf.org or access Liverpool HIV and HEP interaction website http://www.hiv-druginteractions.org www.medicinescomplete.com/mc//indexs/htm, www.medicines.org.uk/emc<br><br>In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given.<br><br>Levonorgestrel should not be given within 5 days of Ulipristal Acetate as the progestogen can theoretically reduce efficacy of Ulipristal Acetate.<br><br>If patient is taking liver enzyme inducers, a Copper IUD should be offered as first line. If it is not appropriate, a 3mg dose of Levonorgestrel should be given. Patient should be informed that efficacy of this is not known. |
| **Cautions** | 1. Pregnancy test may be considered depending on the timing of UPSI within the cycle. If last period was unusual or late, pregnancy test should be recommended. If given inadvertently in pregnancy there is no evidence that this would cause harm<br>2. There is no evidence that Levonorgestrel EC increases the risk of ectopic pregnancy. However as in all early pregnancies in case of failure of oral EC ectopic pregnancy should be ruled out<br>3. Breast feeding- advise to take tablet after feeding and avoid feeding for 8 hours<br><br>In case of doubt, further advice must be sought from an appropriate health professional and recorded in the notes prior to administration of the medication |
| **Exclusion criteria** | 1. Allergy to any of the constituents of Levonorgestrel 1.5mg |

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| | 2. Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption (Levonorgestrel 1.5mg contains 142.5 milligrams of lactose)<br>3. Has taken Ulipristal Acetate in the last 5 days<br>4. If client is under 16 years and not competent by Fraser guideline<br>5. If client is under 13 years of age, refer to GP/sexual health services and follow child protection procedures https://www.tamesidesafeguardingchildren.org.uk/<br>6. Severe malabsorption syndrome (Crohn`s disease)<br>7. Severe liver disease<br>8. Last episode of UPSI more than 96 hours previously<br>9. Unexplained bleeding. |
| **Action if excluded** | Refer to GP or to local Sexual Health Service |
| **Action if client declines** | Document refusal and course of action taken in local protocol. Give advice about alternative sources of treatment and refer as appropriate |

| **Description of Treatment – Levonorgestrel 1.5mg** | |
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| **Name, Form & Strength of medicine** | Levonorgestrel 1.5mg |
| **Legal Category** | Prescription only medicine (POM) |
| **Dosage** | Single dose of 1 tablet of 1.5mg tablet<br><br>If on liver enzyme inducers – 2 tablets of 1.5mg tablet<br>If BMI >26kg/$m^2$ or weight >70kg - 2 tablets of 1.5mg tablet |
| **Route/Method** | Oral |
| **Frequency** | Once, although a second dose may be given if vomiting occurs within 3 hours |
| **Total Dose / number** | One or two tablets as detailed above. Repeated once as indicated above. |
| **Counselling** | 1. **Method**: Single tablet to be taken orally as soon as possible within 72 hours of UPSI (licensed) or 96 hours (unlicensed). Preferably to be taken on site.<br><br>2. **Mode of action**: Mainly by inhibiting ovulation or causing ovulatory dysfunction if given before ovulation<br><br>3. **Failure rate:** The failure rate depends on the timing of UPSI in the cycle, and on how soon after UPSI the EC is taken. Studies show that the pregnancy rate after Levonorgestrel EC taken within 72 hours ranges from about 0.6-2.6%.<br><br>4. **Effect on foetus:** If the method fails there is no evidence that it will have any effect on the foetus. However a normal outcome to any pregnancy cannot be guaranteed<br><br>5. **Other side effects:** Possible nausea, vomiting, breast tenderness, dizziness lower abdominal pain, or headaches, menstrual irregularities |

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| | 6. **Next period:** may be early or late, lighter or heavier than usual<br>7. **Vomiting:** If occurs within 3 hours of taking, a repeat dose is advised<br>8. **IUD:** is more effective and should be discussed with all clients. Levonorgestrel 1.5mg or Ulipristal Acetate 30mg should be given even if client is considering a copper IUD as emergency method of contraception<br>9. **For over phone** consultations check patient name, DoB, address and consent to have medicine delivered (record all details including consent). Ensure delivery occurs in a timely manner. Ensure phone call is undertaken in a confidential manner and uninterrupted. |
| **Information on Follow up** | 1. Clients should be advised to have a pregnancy test if their expected menstruation is more than 7 days late, or lighter than usual. If she has been quick-started with a hormonal contraceptive then a pregnancy test is advised 3 weeks after her last unprotected sexual intercourse. If there is any doubt about menstruation a pregnancy test is advised 3 weeks after last UPSI<br>2. Information about local sexual health services should be supplied as appropriate. https://www.tameside.gov.uk/health/sexualhealth<br>3. The client should also be advised to attend her GP, a sexual health clinic or A&E if she has severe abdominal pain or unexpectedly heavy bleeding<br>4. Future contraception: A regular method of contraception should be discussed. If she is taking COC she should continue with her current packet immediately and use a barrier method for 7 days. If she is taking POP she should continue and use a barrier method for 2 days and if she is taking Qlaira, she should continue and use a barrier method for 9 days<br>5. Safe sex and screening for STIs, including chlamydia, should be discussed and offered as appropriate |
| **Adverse event** | 1. Advise women to report any adverse reaction as per manufacturer's leaflet<br>2. For list of adverse effects refer to Summary of Product Characteristics (SPC) on www.medicines.org.uk or refer to the current edition of BNF<br>3. Refer to GP/local sexual Health service/A & E<br>4. Any adverse event should be recorded in the PMR (patient medication record) and GP informed with client consent<br>5. All relevant adverse effects should be reported under the Yellow Card Scheme (Medicines and Healthcare products Regulatory Agency) |
| **Side effects** | See 'counselling' and also refer to most current BNF/SPC for full details |
| **Interaction with other medicinal products** | Please refer to most current BNF appendix 1 www.bnf.org for full details and www.hiv-druginteractions.org |
| **Specify method of recording** | Pharmacist need to document consultation in PharmOutcomes and label product via PMR |

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| **supply/administration to enable audit trail** | |
| **Storage** | Store in original packaging to protect from light |

| **REFERENCES** | |
|---|---|
| **1.** | Department of Health (2004) *Revised guidance for health professionals on the provision of contraception to under 16's* http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Pressreleases/DH_4086804 |
| **2.** | Department of Health (2009) Reference guide to consent for treatment (2nd edition) |
| **3.** | Faculty of Sexual and Reproductive Healthcare (FSRH) (2014). Service Standards on obtaining valid consent in sexual health services |
| **4.** | Faculty of Sexual and Reproductive Health Care Clinical effectiveness Unit *Emergency Contraception Guidance* (Mar 2017) Available from http://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ |
| **5.** | Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit (CEU) . *Drug Interactions with Hormonal Contraception*. (January 2017) Available from https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal |
| **6.** | Faculty of Sexual and Reproductive Healthcare (FSRH) (2010). Quick Starting Contraception (2017) http://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/ |
| **7.** | Faculty of Sexual and Reproductive Health Care (2014) *Service Standards for Record Keeping* Available from www.fsrh.org.uk |
| **8.** | Levonelle Summary of Product Characteristics. available at www.medicines.org.uk |
| **9.** | Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. *Missed pills: CEU Guidance* (March 2020, amended July 2021). Available from https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-guidance-recommended-actions-after-incorrect-use-of/ |
| **10.** | Faculty of Sexual and Reproductive Health Care, Clinical Effectiveness Unit. *Contraceptive Choices for Young People* .Clinical Guidance. March 2010 Available from http://www.fsrh.org/pdfs/ceuGuidanceYoungPeople2010.pdf |
| **11.** | BNF current version www.bnf.org |
| **12.** | Faculty of Sexual and Reproductive Healthcare (FSRH) (2016). United Kingdom Medical Eligibility Criteria for Contraceptive Use. http://www.fsrh.org/standards-and-guidance/external/ukmec-2016-digital-version/ |
| **13.** | Guidance on the provision of pharmacy services affected by religious moral beliefs https://www.pharmacyregulation.org/regulate/article/guidance-religion-personal-values-and-beliefs |
| **14.** | GPC In practice: Guidance on raising concerns https://www.pharmacyregulation.org/sites/default/files/document/in-practice-guidance-on-raising-concerns-november-2020.pdf |

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| **15.** | CPPE Safeguarding children and vulnerable adults: a guide for the pharmacy team e-learning programme https://www.cppe.ac.uk/services/safeguarding |

**Patient Group Directions for the Administration of Levonorgestrel 1.5 mg**

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR THE SUPPLY OF Levonorgestrel 1.5 mg

## Individual Authorisation

The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer. The healthcare professional retains a copy of the PGD. The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them.

By signing this PGD you are agreeing that:

- You have read and understood the content
- To the best of your knowledge, the content of the PGD is correct and supports best practice
- You will act within the parameters of the PGD
- You take responsibility for maintaining your competence and on-going training requirements to continue to use the PGD safely

Named Healthcare Professional_____

Designation_____

**The above named healthcare professional is authorised to work within the confines of this PGD**

Name of Employer/ Contractor_____

Address of Employer/ Contractor_____

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Signature of Employer/ Contractor_____

**I, the undersigned, have read and understood this PGD and agree to work within its confines**

Signature of Named Healthcare Professional_____

Date _____

**One copy to be retained by the named healthcare professional**
**One copy to be retained by the employer / contractor**
**The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.**

**Table 1**
**Indication for EC following potential failure of hormonal or intrauterine contraception**

| Method | Possible failure of HC | Indication for EC |
|---|---|---|
| Hormonal methods of contraception | Failure to use additional contraceptive precautions when starting the method | UPSI or barrier failure during time that additional precautions required as indicated within CEU guidance. |
| Combined hormonal transdermal patch or combined hormonal vaginal ring | Patch detachment/ring removal for >48 hours<br><br>Extension of patch-free or ring-free interval by >48 hours | EC is indicated if patch detachment or ring removal occurs in Week 1 and there has been UPSI or barrier failure during the hormone-free interval (HFI) or Week 1.<br><br>If the HFI is extended, a Cu-IUD can be offered up to 13 days after the start of the HFI assuming previous perfect use .<br><br>If CHC has been used in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC |
| Combined oral contraceptive pill (monophasic pill containing ethinylestradiol) | Missed pills (if two or more active pills are missed) | EC is indicated if the pills are missed in Week 1 and there has been UPSI or barrier failure during the pill-free interval or Week 1.<br><br>If the pill-free interval is extended (this includes missing pills in Week 1), a Cu-IUD can be offered up to 13 days after the start of the HFI assuming previous perfect use.<br><br>If COC has been taken in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC |
| Combined hormonal contraception, progestogen-only pill and progestogen-only implant | Failure to use additional contraceptive precautions whilst using liver enzyme inducing drugs or in the 28 days after use | EC is indicated if there is UPSI or barrier failure during, or in the 28 days following, use of liver enzyme-inducing drugs.<br><br>Offer a Cu-IUD (unaffected by liver enzyme-inducing drugs) or a double dose (3 mg) of LNG-EC.<br><br>UPA-EC is not recommended with enzyme inducing drugs |
| Progestogen-only pill | Late or missed pill (>27 hours since last traditional POP or >36 hours since last desogestrel-only pill) | EC is indicated if a pill is late or missed and there has been UPSI or barrier failure before efficacy has been re-established (i.e. 48 hours after restarting).<br><br>Timing of ovulation after missed pills cannot be accurately predicted. A Cu-IUD is therefore only recommended up to 5 days after the first UPSI following a missed POP (see Section 13.2.1). |

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| | | If POP has been taken in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC |
| Progestogen-only injectable | Late injection (>14 weeks since last injection of DMPA) | EC is indicated if there has been UPSI or barrier failure:<br>• >14 weeks after the last injection<br>• within the first 7 days after late injection<br><br>Timing of ovulation after expiry of the progestogen-only injectable is extremely variable.<br><br>A Cu-IUD is only recommended up to 5 days after the first UPSI that takes place >14 weeks after the last DMPA injection.<br><br>The effectiveness of UPA-EC could theoretically be reduced by residual circulating progestogen. Consider use of LNG-EC |
| Progestogen-only implant | Expired implant | Effectiveness of UPA in the presence of progestogen is not known. Can consider LNG –EC with quick start or UPA with start of HC 5 days later |
| Intrauterine contraception (Cu-IUD and LNG-IUS | Removal without immediate replacement; partial or complete expulsion; threads missing and IUC location unknown<br><br>Expired IUS | If UPSI has taken place in the 5 days prior to removal, perforation, partial or complete expulsion.<br><br>Depending on the timing of UPSI and time since IUD known to be correctly placed, it may be appropriate to fit another Cu IUD for EC<br><br>Effectiveness of UPA in the presence of progestogen is not known. Can consider LNG –EC with quick start or UPA with start of HC 5 days later |

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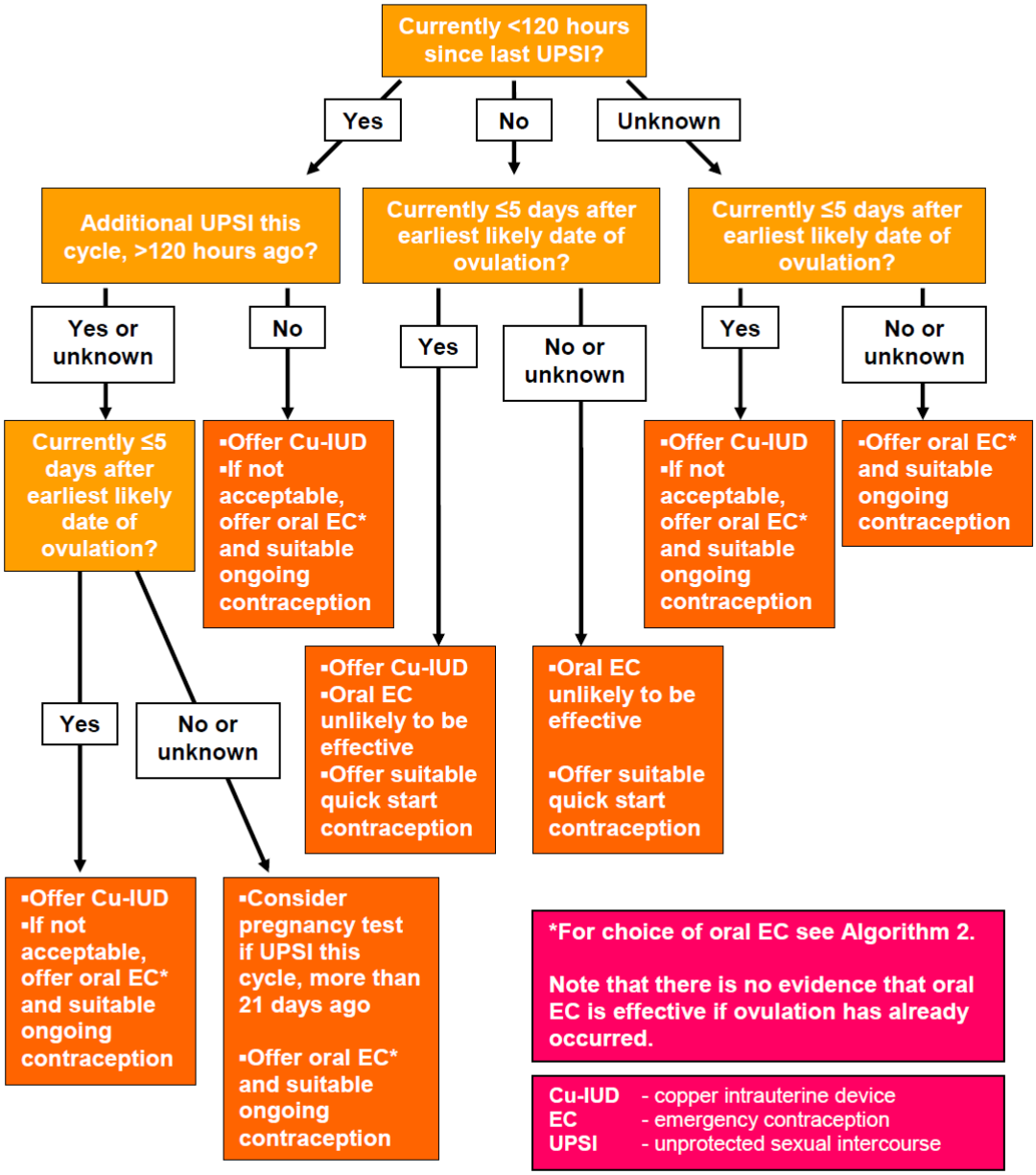
## Decision-making Algorithms for Emergency Contraception

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

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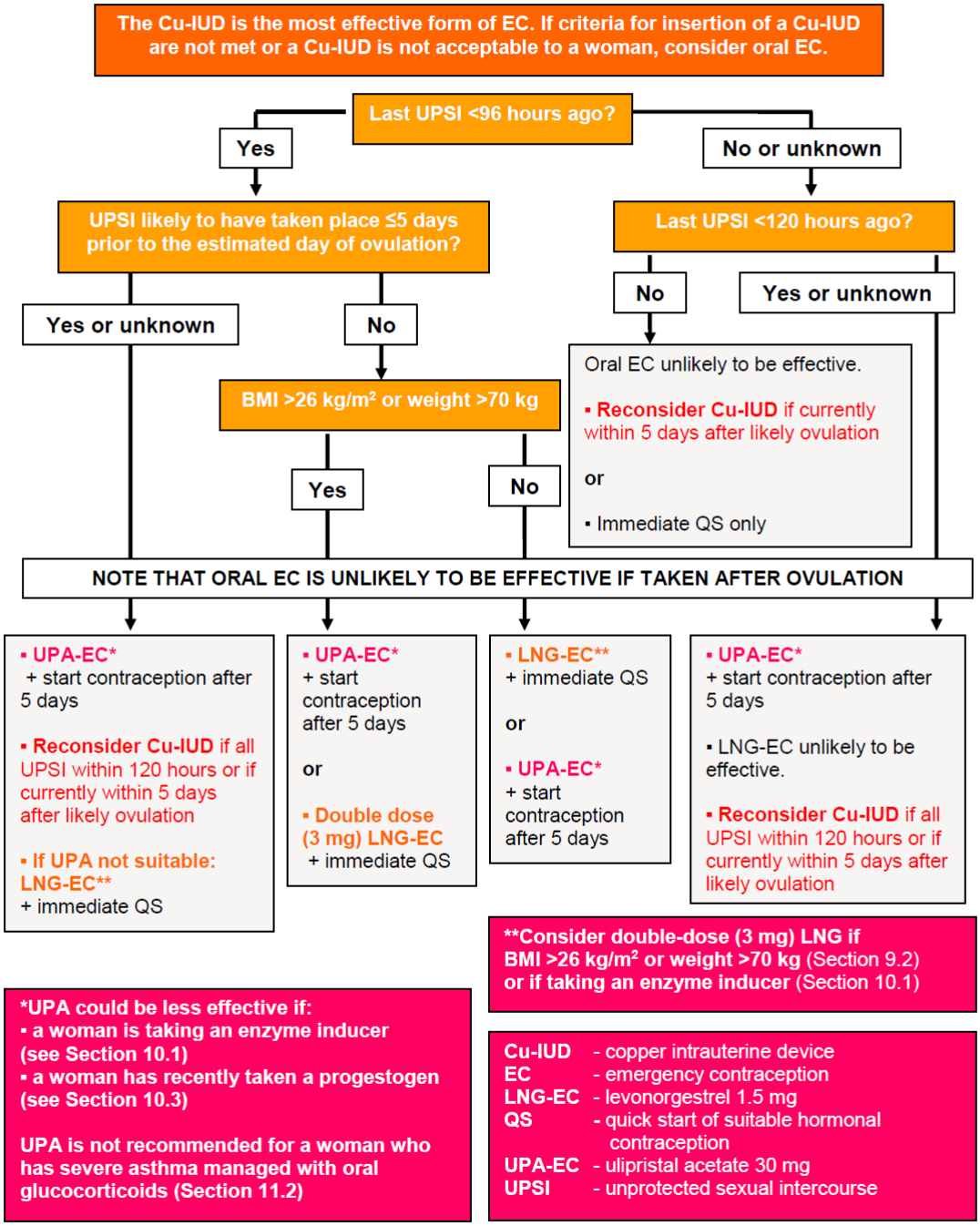
**Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)**

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