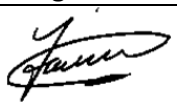
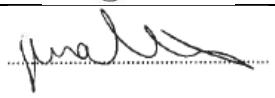
Patient Group Directions for Supply and Administration of Uliprisal acetate 30mg tablet Progestogen-only Emergency Hormonal Contraception (EHC)
By
Accredited Pharmacist from Community Pharmacies contracted with Population Health Tameside

PATIENT GROUP DIRECTIONS
FOR THE ADMINISTRATION OF
Ulipristal acetate 30 milligrams (mg)
POM (Prescription only medicine)

These directions are a legal requirement for 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 and each individual pharmacist and then signed by both parties. In the managed service they should be agreed by the person to work under the direction and the manager of this person. A copy should be retained in a safe place available for use at all relevant 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 NHS Greater Manchester Integrated Care – Tameside		11 May 2023
Dr Matthew Johnson	Public Health Clinical Lead (Primary Care - Sexual Health) Tameside MBC		11 May 2023
James Mallion	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 Ulipristal acetate 30 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 Ulipristal acetate 30 mg

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR SUPPLY OF Ulipristal Acetate (UPA) 30mg

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

Clinical Details – **Ulipristal Acetate 30 mg**	
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. This PGD should be used in conjunction with the PGD for Levonorgestrel (LNG) 1.5 mg. 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.
Inclusion criteria	This service is available to clients aged 13 years and over (If under 16 meets the Fraser Guidelines) deemed competent to consent to treatment. If safeguarding concerns are identified in any client under 18 years referral should be made in line with local policy/procedures. Ulipristal 30mg can be used in the following circumstances: - Client presenting within 120 hours of unprotected sexual intercourse (UPSI) or failed barrier method which is likely to have been in the 5 days before the likely date of ovulation in a natural menstrual cycle. A margin of error should

	be allowed when estimating the date of ovulation. If it is not possible to establish date of ovulation, use of Ulipristal (UPA) as EC should be considered. Note that ovulation can be expected up to day 19 of a 28 day cycle. - Client presenting within 96-120 hours of UPSI or failed barrier method regardless of time in the cycle - Client presenting within 120 hours of UPSI or failed barrier method with a body mass index (BMI) of >26 kg/m^2 or weight >70kg regardless of time in the cycle. - Following potential failures or non-compliance of hormonal contraception. Refer to Table 1in appendices. NB: If hormonal contraception is taken in the preceding 7 days, UPA should not be given. Hormonal contraception should not be re-started within 5 days of taking UPA - Following potential failure of intrauterine device (IUD) or system (IUS). Refer to Table 1 in appendices. - Post-partum: UPSI 21 days or more post-delivery (unless meets criteria for lactational amenorrhoea). If breast feeding advised to avoid or express and discard for 7 days after UPA. - Post Termination of pregnancy, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease: UPSI or failed barrier method after 5 days or later. In all cases IUD should be discussed and referral offered. If the client is within 120 hours of risk, or 120 hours of earliest predicted time of ovulation, an emergency IUD is the treatment of choice. If referred on for emergency IUD, Levonorgestrel or Ulipristal acetate should still be administered if within the confines of the available PGDs.
Use outside the Terms of the Marketing Authorisation License	In the following circumstances, Ulipristal acetate 30 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. a. Client vomits within 3 hours of taking the tablet b. The Clinical effectiveness Unit of the Faculty of Sexual and Reproductive Health recommends that UPA can be used more than once in the same cycle and can be used with a risk of pregnancy, as there is no evidence to indicate UPA increases the risk of miscarriage or developmental 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 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. If Levonorgestrel or any progestogen has been taken in the previous 7 days, UPA should not be used as the progestogen can theoretically reduce the efficacy of UPA. No medication containing progesterone should be started within 5 days of taking UPA as this can theoretically reduce the efficacy of UPA. If patient is taking liver enzyme inducers, UPA is not recommended. A copper IUD should be offered as first line. If it is not appropriate, double dose of Levonorgestrel (LNG) should be given (Refer to LNG PGD). The absorption of Ulipristal may be reduced by drugs that raise gastric pH (including proton pump inhibitors, antacids and H2-receptor antagonists).[5] The clinical relevance of this interaction for single dose administration of Ulipristal Acetate as emergency contraception is not known. In patients who are already taking these drugs, it is therefore advisable to offer Levonorgestrel or the IUD as an alternative.
Cautions	1. Pregnancy test may be considered depending on the timing of the risks 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. 2. There is no evidence that UPA EC increases the risk of ectopic pregnancy more than in the general population (0.8-2%). In case of failure of EC ectopic pregnancy should be ruled out 3. Severe malabsorption syndrome (Crohn`s disease) 4. Breast feeding- advise to stop feeding or express and discard breast milk for 7 days after taking UPA 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 UPA 2. Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption (Each tablet contains 237 milligrams of lactose monohydrate) 3. Has taken Levonorgestrel EHC or any progestogens in the last 7 days 4. On liver enzyme inducers currently or within the last 28 days 5. Severe hepatic impairment 6. Severe asthma managed with oral glucocorticoids 7. If client is under 16 years and not competent by Fraser guideline 8. If client is under 13 years of age- refer to GP/sexual health services and follow child protection procedures. https://www.tamesidesafeguardingchildren.org.uk/

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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 – Ulipristal acetate 30 mg	
Name, Form & Strength of medicine	Ulipristal acetate 30mg
Legal Category	Prescription only medicine (POM)
Dosage	Single dose of 1 tablet of 30 mg tablet
Route/Method	Oral
Frequency	Usually once, although a second dose may be given if vomiting occurs within 3 hours
Total Dose / number	One tablet
Counselling	1. **Method**: Single tablet to be taken orally as soon as possible within 120 hours of risk (licensed). Preferably to be taken on site. 2. **Mode of action**: acts by delaying ovulation for at least 5 days until sperm from UPSI are no longer viable. It cannot prevent a pregnancy once ovulation has already occured. 3. **Failure rate:** The failure rate depends on the timing of risks in the cycle, and on how soon after risk the EC is taken. Studies show that the pregnancy rate is 1-2%. The number of pregnancies prevented by UPA has been estimated to be 60-80% in different studies. 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 5. **Other side effects:** Possible nausea, vomiting, breast tenderness, dizziness lower abdominal pain, or headaches 6. **Next period:** may be early or late, lighter or heavier than usual 7. **Vomiting:** If occurs within 3 hours of taking, a repeat dose is advised

	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. 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	10. Clients should be advised to have a pregnancy test if their expected menstruation is more than 7 days late, or lighter than usual. If there is any doubt about menstruation a pregnancy test is advised 3 weeks after last UPSI. If they have been started with a hormonal contraception 5 days after taking UPA pregnancy test is advised 3 weeks after her last unprotected sexual intercourse. 11. Information about local sexual health services should be supplied as appropriate. https://www.tameside.gov.uk/health/sexualhealth 12. 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 13. Future contraception: A regular method of contraception should be discussed. Any hormonal contraception containing progestogen should be started after 5 days therefore use barriers or abstain for this time. If commenced on COC she should use a barrier method for 7 days, if on POP for 2 days and if on Qlaira for 9 days. 14. Safe sex and screening for STIs, including chlamydia, should be discussed and offered as appropriate
Adverse event	1. Refer to GP/local sexual Health service/A & E 2. Advise women to report any adverse reaction as per manufacturer's leaflet 3. 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 4. Any adverse event should be recorded in the PMR (patient medication record) and GP informed with client consent 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	UPA interferes with progestogen containing medication Please refer to most current BNF appendix 1 www.bnf.org for full details and www.hiv-druginteractions.org

Specify method of recording supply/administration to enable audit trail	Pharmacist need to document consultation in PharmOutcomes and label product via PMR
Storage	Store in original packaging to protect from light

Patient Group Directions for the Administration of Ulipristal acetate 30 mg

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.	Ulipristal acetate 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
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 Ulipristal acetate 30 mg

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR THE SUPPLY OF Ulipristal acetate 30 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 establishing and 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_____

_____

_____

_____

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.

Patient Group Directions for the Administration of Ulipristal acetate 30 mg

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

UPA is licensed for use within 5 days (120 hours) after UPSI or contraceptive failure.

Please note that if progestogen containing contraception has been taken in the 7 days prior to presentation Ulipristal is not recommended, as the progestogen may reduce the efficacy of the UPA

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 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. 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 . 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. 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. 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. Offer a Cu-IUD (unaffected by liver enzyme-inducing drugs) or a double dose (3 mg) of LNG-EC. UPA-EC is not recommended with enzyme inducing drugs
Progestogen-only pill	Late or missed pill (>27 hours since last traditional POP or >36	EC is indicated if a pill is late or missed and there has been UPSI or barrier failure before efficacy

	hours since last desogestrel-only pill)	has been re-established (i.e. 48 hours after restarting). 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). 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: • >14 weeks after the last injection • within the first 7 days after late injection Timing of ovulation after expiry of the progestogen-only injectable is extremely variable. A Cu-IUD is only recommended up to 5 days after the first UPSI that takes place >14 weeks after the last DMPA injection. 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 Expired IUS	If UPSI has taken place in the 5 days prior to removal, perforation, partial or complete expulsion. 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 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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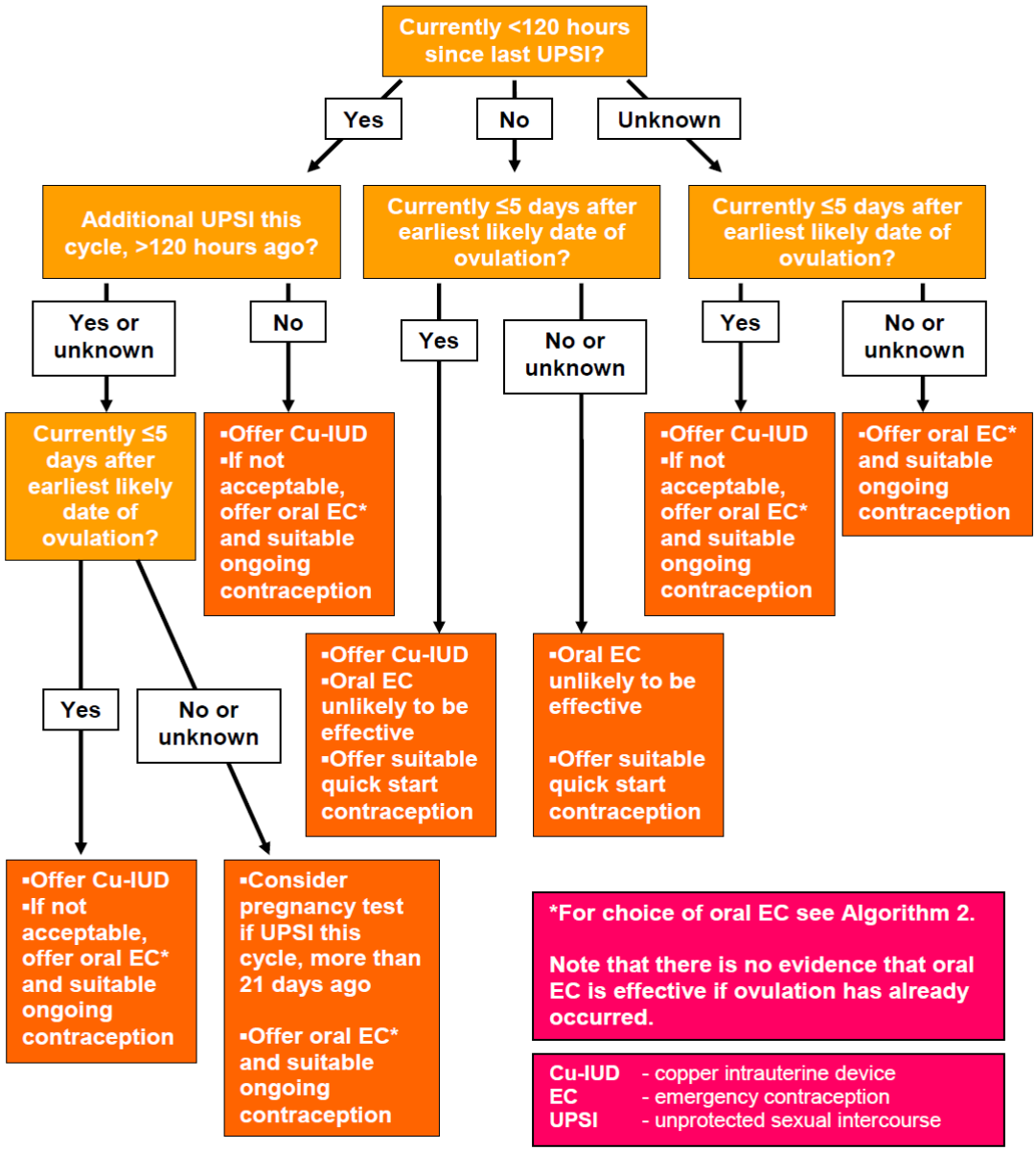
Decision-making Algorithms for Emergency Contraception

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



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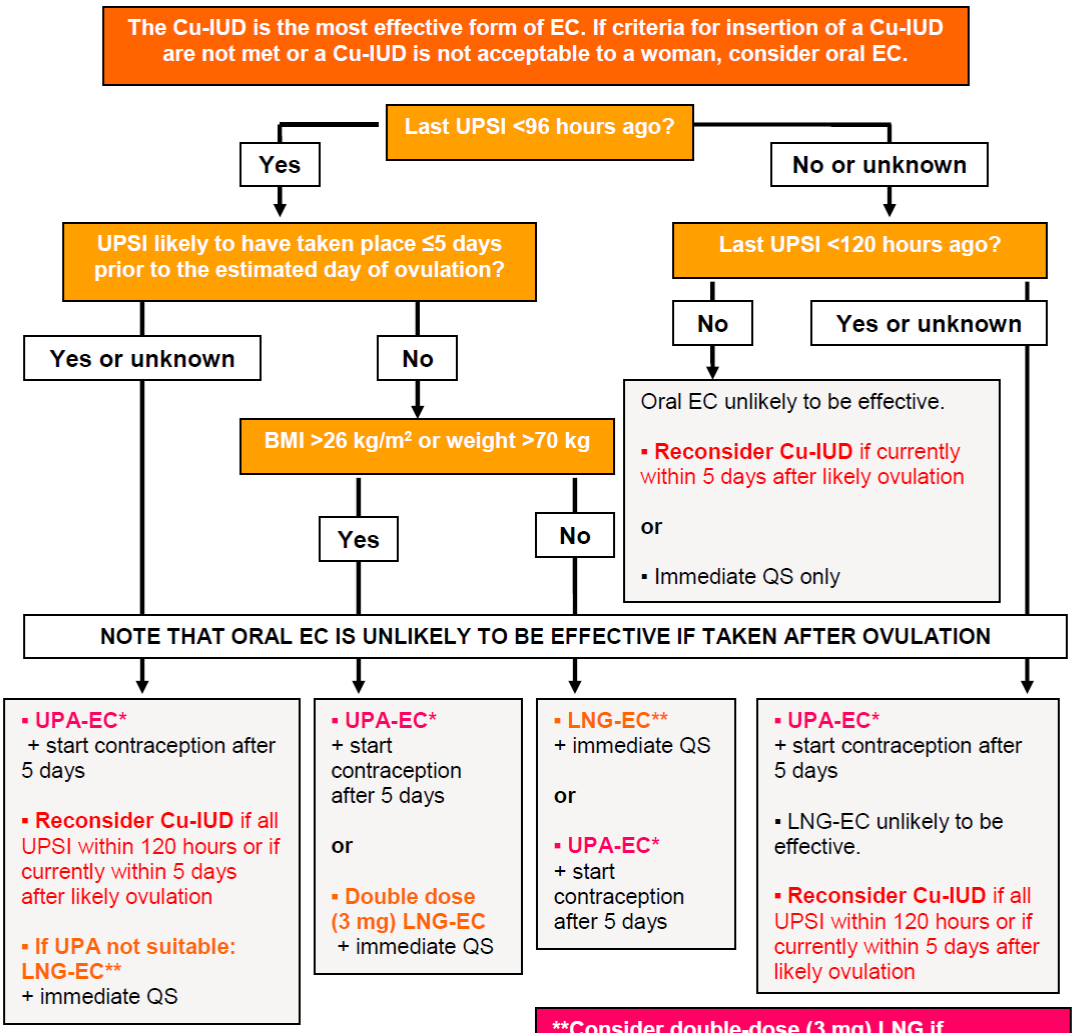
Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)



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