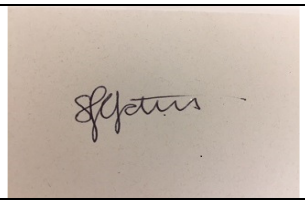
Patient Group Direction (PGD) for the Supply of

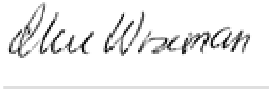
ULIPRISTAL 30MG TABLET as Hormonal Emergency Contraception (EHC)

by Registered & Accredited Pharmacists to Individuals Accessing the Gateshead Council EHC Service from Commissioned Community Pharmacies Gateshead Council (GC)

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

Direction Number: - **GCP 2021/02C**
Valid from: **1st April 2021**
Review date: 1st February 2023
Expiry date: 31st March 2023

This PDG has been developed & produced by:-			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author)	Sue White North of England Commissioning Support		26.3.2021
Senior Doctor	Dr Sarah Gatiss, Sexual Health Contraception Lead O&G Consultant Dr		25/3/21
Local Authority Sexual Health Programme Lead	David Brady Gateshead Public Health		26/03/21
Local Pharmaceutical Committee representative	Sami Hanna Communications Officer Gateshead & South Tyneside LPC		26/03/21

This PGD has been approved for use in Gateshead Council by:			
Title	Name	Signature	Date
Director of Public Health Gateshead Council	Alice Wiseman		26/03/21

1. Clinical Condition or Situation to which the Direction Applies

Indication (defines situation or condition)

- Female patients at risk of unwanted pregnancy requesting emergency hormonal contraception (EHC) within 120 hours of unprotected sexual intercourse (UPSI) or failed contraceptive method since last menstrual period

Objectives of care

- To prevent pregnancy **(NB. ADVANCE SUPPLY IS NOT INCLUDED IN THIS PGD)**

Inclusion criteria

(Only use those criteria that are specific to your authorised role & competence. Ensure appropriate consent has been obtained or a best interest decision is in place before commencing any supply). Please also see notes below†.

Competent women aged 14 and over requesting EHC and one or more of the following criteria apply: -

1. Presents within 120hrs of UPSI or within 120hrs of USPI due to potential failure of a contraceptive method listed below and the client is either
   - aged 16 and over (assess formerly if competence in doubt) **or**
   - aged 14 or 15 years and considered to be Fraser competent by satisfying the assessment within the Fraser Guidance (see Appendix 1).

   Possible failure/reduced efficacy of contraceptive methods include:
   - Potential barrier method failure
   - Severe gastrointestinal upset that may have affected contraceptive efficacy (see current BNF), including vomiting within 3 hours of taking a Ulipristal (UPA) Emergency Contraception (EC) preparation
   - Risk of conception whilst advised to avoid pregnancy, such as following administration of cytotoxic agents or potentially teratogenic drugs.
   - Missed/delayed/failed combined contraceptive pill (COC)/patch or progesterone only pill (POP) - refer to FSRH Recommended Actions after incorrect Use of Combined Hormonal Contraception (e.g. late or missed pills, ring and patch) (March 2020) https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-guidance-recommended-actions-after-incorrect-use-of/
   - Late injection (>14 weeks since last injection of depo medroxyprogesterone acetate (DMPA) such as Depo Provera and Sayana Press or >10 weeks since depo norethisterone enanthate (NET-EN) and UPSI during time that extra precautions were required.)
   - Risk of conception whilst advised to avoid pregnancy, such as following administration of cytotoxic agents or potentially teratogenic drugs.
   - Failure to use additional contraceptive precautions when starting hormonal methods of contraception
   - Women who are taking oral contraception who have also taken prescribed, or OTC medication that is known to interact with their oral contraception (producing a reduced effect).
   - Failure to use additional contraceptive precautions (or barrier failure) to Combined Hormonal Contraception (CHC), Progestogen Only Pill (POP), Progestogen only implant, whilst using liver enzyme-inducing drugs or in the 28 days after use, e.g. concomitant use of enzyme inducing rifamycins (such as rifabutin and rifampicin) and CHC. EHC is not required when using (CHC) with antibiotics that are not enzyme inducers. Please also see section entitled 'Precautions' for recommended action.'
   - Failed to use an additional barrier method of contraception when current methods have failed or been missed.
   - Can confirm that their intrauterine contraceptive device (IUCD)/IUS is not present, displaced or expelled or subdermal implant has expired. This would indicate that their current method cannot be relied on, and client has not used additional contraception.
2. Those who have vomited within 3 hours of taking UPA-EC pill, providing the new dose is still within 120 hours of the UPSI that the previous dose was given for.
3. The client's medical history indicates prophylaxis is appropriate, (i.e. following assessment, discussion and informed choice (including provision of information about efficacy, adverse effects, interactions, medical eligibility and

contraindications, and additional contraceptive precautions), they request Ulipristal 30mg as the preferred emergency contraception method).

4. Is presenting within 120 hours of UPSI and there has been an earlier episode of UPSI **>120hours ago** in the same menstrual cycle, whether oral EC **was** given or not. If the previous UPSI was **> 21 days ago** and the woman has had no period, there must be a negative pregnancy test i.e. pregnancy excluded before considering EC. **
5. Women choosing to be referred for a Cu-IUD, where UPA-EC is clinically suitable and supply is not contra-indicated or excluded for reasons listed in the exclusion criteria.
6. If UPSI is likely to have taken place during the 5 days prior to ovulation UPA-EC is considered first line for women having UPSI 0-120 hours ago (even if she has had UPSI within the last 72 hours)

**(Please see note in cautions section).

(Refer to the FRSH Emergency Contraception guidelines[1] for additional information and Appendix 2 for modified decision-making tree.

Exclusion criteria (please also refer to current SPC and latest BNF)

Clients fulfilling one or more of the following criteria are excluded from supply under this PGD: -

- No valid consent /best interest decision in place.
- Where consumption of the dose would be over 120 hours since this episode of UPSI.
- The client is not present. (No third-party supplies are permissible).
- Relevant medical history is not provided by the client.
- Females aged 13 years or younger
- Female not satisfying the pharmacist's assessment for Fraser Competence (see Appendix 1).
- Where previous episode(s) of UPSI has already been treated within this cycle:
  - If UPA –EC used recurrently within the same cycle, continue with UPA-EC if repeated episodes of UPSI
  - If LNG-EC used recurrently within the same, continue with LNG- EC if repeated episodes of UPSI (refer to relevant PGD)
- Post-natal clients presenting within 21 days after giving birth. (UPSI more than 21 days after delivery can lead to pregnancy).
- No menstrual period within the last 24 months.
- Known pregnancy or possibility of pregnancy i.e. last period absent, a current or recent positive pregnancy test **.
- Last menstrual bleed (period) in any way abnormal (different character, length or flow to previous periods) **
- Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).
- Abnormal or unexplained vaginal bleeding.
- Severe hepatic impairment
- Patients with severe asthma controlled by oral glucocorticoids.
- Taking interacting medicines (See BNF Appendix 1 for full list) either currently or within 28 days of completing treatment.
  - Liver enzyme-inducing drugs (See Section 3 Drug Interactions within this PGD and for full details refer to BNF or SPC)
    Please refer to Levonorgestrel (Levonelle One) PGD for alternate EC treatment option.
- Any condition causing severe malabsorption e.g. Crohn's Disease or severe diarrhoea & vomiting.
- Has taken progestogen containing drugs including LNG-EC within the previous 7 days.
- Galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption.
- Concurrent use of antacids, proton-pump inhibitors or H2-receptor antagonists.
- Severe asthma controlled by oral glucocorticoids.
- Any contraindication to Ulipristal 30mg **(see manufacturer's SPC)**
- Known hypersensitivity to any ingredient, component or excipient of the tablet (refer to SPC);
- Where it is unacceptable to patient to delay starting hormonal contraception for 5 days

Refer to current Summary of Product Characteristics (SPC) / BNF (current on-line version)/ latest BNF for full list of details

Cautions/Precautions

There is significant increased risk of pregnancy with further UPSI later in the cycle in which oral EC has been taken. If the woman has had UPSI more than 120 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with UPA-EC following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded.

All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider.

There is now some evidence* that Ulipristal acetate EC (UPA-EC) may be less effective in women with BMI >30 kg/m2 or weight >85 kg.

- In all women, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of the woman's body weight or BMI
- Consideration should be given to whether a dose of ulipristal is suitable or whether a double dose of levonorgestrel is more appropriate (see Levonorgestrel PGD and SPC) .
- **A double dose of ulipristal is NOT recommended for women of any weight or BMI**

**FSRH Guidance: Overweight, Obesity and Contraception (April 2019).* https://www.fsrh.org/documents/fsrh-clinical-guideline-overweight-obesity-and-contraception/

For clients **taking liver enzyme inducing drugs** e.g. carbamazepine, rifampicin, griseofulvin (refer to BNF/SPC for full details), or who have stopped taking this medication within the last 28 days, refer to the Levonorgestrel PGD for possible treatment option. Where this is also unsuitable: refer to Integrated Sexual Health http://www.gatesheadsexualhealth.co.uk/ for Cu-IUD. They should be advised that a Cu-IUD is the only method of EC not affected by these drugs.

- **Breast feeding** is not recommended for 7 days after taking UPA-EC. During this time it is recommended to express and discard the breast milk in order to stimulate lactation.
- **Renal Impairment** – No dose adjustment is necessary (SPC)
- **Malabsorption syndromes** Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of ulipristal is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed.
- Consider **child protection issues** in females aged 13-17 years and any safeguarding issues in those aged 18 years and over.
- **Delay hormonal contraception** for 5 days after taking UPA-EC. Effectiveness of combined hormonal and progestogen-only contraceptives may be reduced—additional precautions (barrier methods) required for 12 days for combined and parenteral progestogen-only hormonal contraceptives (14 days for *Qlaira*®) and 7 days for oral progestogen-only contraceptives.
- Consider risks due to **ovulation timing**.
- When there is suspected **sexually transmitted infection** (STI), refer to Integrated Sexual Health services or their own GP.

Action if excluded

- If consumption of the dose would be beyond 120 hours since this episode of UPSI, refer to Integrated Sexual Health services or GP immediately for consideration of possible alternative prophylaxis (e.g. Cu-IUD).
- If excluded for any other reason, refer to (family planning) Integrated Sexual Health services or GP immediately if emergency contraception considered necessary.
- Ensure all actions/decisions are documented. If treatment is refused, this must be recorded on PharmOutcomes.

Circumstances in which further advice should be sought from a doctor and/or specialist

- Refer to the Integrated Sexual Health services or to GP if medically indicated or at the patient's request.
- If concerns identified regarding safeguarding issues follow local policy & contact safeguarding team for referral support.

Action if patient declines treatment (offer to assist the patient in this process)

- Provide appropriate advice and refer to Integrated Sexual Health services or GP.
- Record the refusal in the PharmOutcomes clinical record and document all other actions taken.

2. Description of Treatment

Name, strength & formulation of drug

Ulipristal 30mg tablet

Legal Status and Storage requirements:

POM – Prescription Only Medicine / **STORAGE**: Do not store above 25°C

Dosage /Dose range

1 x 30mg tablet:
Highest efficacy is achieved if the tablet is taken as soon as possible (and no later than 120 hours) after UPSI.

Route/Method

Oral administration only

Frequency of Administration

One single treatment dose. The client should take the medicine whilst under supervision at the pharmacy.

- NB. If vomiting occurs within 3 hours of taking UPC-EC another Ulipristal 30mg tablet should be taken if it still within 120hours of UPSI. (A maximum of 2 episodes of UPSI may be treated within one menstrual cycle).

Maximum dose & number of treatments

Maximum single dose: - **1 x 30mg tablet**
(If vomiting occurs within 3hrs of taking UPC-EC a second Ulipristal 30mg tablet should be taken if it still within 120hours of UPSI)

Maximum no. of treatments: - 3 separate episodes of UPSI in the same menstrual cycle

Follow up treatment/action

- **A pregnancy test is recommended in three weeks' time.**
- When there is suspected STI, signpost to Integrated Sexual Health testing services if appropriate.
- Inform client that if there is an abnormal period and/or abdominal pain then they should contact their local sexual health services or see their GP.
- Advise any person who has had unprotected sexual intercourse to attend Sexual Health services for a full sexual health screen (testing for chlamydia, GC ,HIV and STS) or see their GP.
- Record keeping – see section below.

Labelling

The packaging should be labelled in the manner of any prescribed medication and contain a manufacturer's patient information leaflet.
Pre-printed labels should allow the client's name and date of dispensing to be added.

3. Further Aspects of Treatment

Drug Interactions

- Concomitant use of UPA-EC and drugs containing LNG are not recommended
- The effectiveness of UPA-EC is reduced in women taking enzyme-inducing drugs and for up to 4 weeks after stopping. Therefore, UPA-EC is not recommended. A Cu-IUD should be recommended for these women or LNG-EC.
  Examples of enzyme inducing drugs include:
  - Antiepileptics: carbamazepine, eslicarbazepine, oxcarbazepine, phenobarbital, phenytoin, griseofulvin, rufinamide, topiramate
  - Antibiotics: rifampicin and rifabutin
  - Antiretrovirals: always use the HIV Drug interaction checker (www.hiv-druginteractions.org)
  - Antidepressants: St John's Wort
  - Others: modafinil, bosentan, aprepitant
- For the above patients where EC is considered necessary, then they should seek suitable healthcare provision immediately, e.g. Integrated Sexual Health services or GP where a Cu-IUD can be offered instead.
- The manufacturer has noted that the effectiveness of Ulipristal may be reduced in women taking drugs PPI's such as esomeprazole although the clinical relevance of this interaction for a single dose administration of UPA-EC is not known.

Use the yellow card system to report adverse drug reactions directly to the MHRA **(see BNF)**

This list is not exhaustive. Please also refer to current BNF, manufacturers SPC and FRSH Guidance for details of all interactions

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See manufacturers SPC for full details / current BNF

- Failure rate and efficacy.
- The risk of pregnancy is highest after UPSI that takes place during the 5 days leading up to and including the day of ovulation. Insertion of a Cu IUD within 5 days of the earliest estimated date of ovulation is the only method of EC that is effective after ovulation has taken place.
- Possible effects on menstrual cycle. Discuss what to do if period does not arrive/or is unusual (see management of adverse drug reactions (ADRs) below.
- Seeking medical advice promptly if any lower abdominal pain occurs.
- Then explain/discuss the potential side effects, and the likelihood of them occurring (see below; adverse effects/reactions.

Potential Adverse Effects/ Reactions: -

Well tolerated, however common side effects that some clients may experience include:

- **Nausea** – advise medication to be taken with food.
- **Vomiting** – provide clients with clear instructions for obtaining an additional tablet if vomiting occurs within 3 hours of the dose being taken.
- **Other adverse reactions** include: breast tenderness, lower abdominal pain, headaches, dizziness, diarrhoea and fatigue. Bleeding patterns may be temporarily disturbed e.g. bleeding, spotting, delayed or early next period.

This list is not exhaustive. Please also refer to current BNF and manufacturers SPC for details of all potential adverse reactions
Use the yellow card system to report adverse drug reactions directly to the MHRA **(see BNF)**

Identification and Management of Adverse Reactions

- Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected date. If the next menstrual period is more than 7 days overdue, if it is abnormal in character or if there are symptoms suggestive of pregnancy, pregnancy should be excluded.

In the event of untoward or unexpected adverse reactions:

- If necessary seek appropriate emergency advice and assistance.
- Document in the Patient Medication Record (PMR) and inform GP.

Reporting Procedure of Adverse Effects

- See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.
- Client to report any suspected ADRs believed to be associated with Ulipristal 30mg tablet to a Healthcare Professional or directly using the Yellow Card system.

  Clients and Healthcare Professionals can log ADRs directly via the MHRA website (http://yellowcard.mhra.gov.uk/) or call freephone 0808 100 3352 (10am to 2pm Monday-Friday only).

Additional Information and Facilities

- UPA-EC should be considered first line oral EC for a women who has had UPSI 72-120hrs ago.
- UPA-EC should be considered first line oral EC for a women who has had UPSI within the last 5 days if the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation. (FSRH, page vii)
- UPA-EC can delay ovulation even after the start of the LH surge, a time when LNG-EC is no longer effective.
- Have access to the current PGD, updated FSRH Emergency Contraception Guideline latest SPC & BNF.

Advice to Patient (verbal or written)

Advice to all clients:

- Give advice on the options for emergency contraception (EC) as per the decision tree. Provide information and advice on UPA-EC and the Cu-IUD to allow the client to make an informed choice regarding treatment (see decision tree). Advise the client that the Cu-IUD is the most effective form of EC.
- Advise the client to discuss sexual health matters and contraception with a suitable healthcare professional at their GP surgery or Integrated Sexual Health services.
- Standard contraceptive methods are the first line in contraception. Emergency contraception should only be used in emergencies. Whilst repeated doses of Ulipristal can be given in one cycle, there is a risk of interruption of the menstrual cycle, hence repeated courses of EHC are not the best form of contraception.

Also, the patient must be given advice on:

- **Mode of action** – Inhibition or delay of ovulation
- **Failure rate** - UPA-EC demonstrated to be effective for EC up to 120hours
  - Efficacy of UPA-EC is non-inferior to that of LNG-EC when presenting between 0-72hrs after UPSI.
  - EC provided after ovulation is ineffective (FSRH, page viii).
  - UPA-EC more effective than LNG-EC when taken within 120 hours of UPSI (see table below):

  Two RCTs (see Table) showed the efficacy of UPA to be non-inferior to that of LNG in women who presented for EC between 0 and 72hrs after UPSI or contraceptive failure. Combined data from both RCTs via meta- analysis, shows the risk of pregnancy with UPA was significantly reduced compared to LNG (p=0.046). [3]

Randomized controlled trial	Pregnancy rate (%) within 72h of unprotected intercourse or contraceptive failure		Odds ratio [95% CI] of pregnancy risk, ulipristal acetate vs levonorgestrel
	Ulipristal acetate	Levonorgestrel	
HRA2914-507	0.91 (7/773)	1.68 (13/773)	0.50 [0.18-1.24]
HRA2914-513	1.78 (15/844)	2.59 (22/852)	0.68 [0.35-1.31]
Meta- analysis	1.36 (22/1617)	2.15 (35/1625)	0.58 [0.33-0.99]

- **Side effects** - Provide advice regarding vomiting or severe diarrhoea within 3 hours of taking the tablets.
- **Possible effects on foetus** – Evidence is limited, but no evidence of adverse pregnancy outcomes or foetal abnormality, if a pregnancy occurs due to a failure of UPA-EC. There can be however never be a guarantee of healthy pregnancy outcome for any pregnancy but. If UPA-EC has been taken in a cycle in which pregnancy is conceived, it should be reported to www.hra-pregnanct-registry.com.
- **Risk of ectopic pregnancy** - if pregnancy does occur, the possibility of an ectopic pregnancy should be considered. Inform the patient to seek prompt medical advice if any abdominal pain occurs. NB. The rate of ectopic pregnancy when UPA-EC failed did not exceed that of the general population i.e. i.e. there is no increased risk of ectopic pregnancy occurring it UPA-EC fails
- **Breast-feeding** – the drug is excreted into breast milk. Advise patient not to breast feed for 1 week after using UPA-EC. The milk may be expressed and discarded during that time.
- **Dose** - oral EC is most efficacious the earlier it is taken (after UPSI). The dose should be taken under pharmacist supervision.
- **Follow-up** – advise a pregnancy test in 3 weeks after taking UPA-EC
- **Contraception for the remainder of cycle** - Advise client to abstain from sexual intercourse or use a barrier method correctly and consistently until next period. EC does NOT provide contraceptive cover for the remainder of this menstrual cycle. SPC states that although use of UPA (ellaOne) does not contraindicate the continued use of regular hormonal contraception. Woman wishing to start or continue hormonal contraception can do so after using UPA, however, they should be advised to use a reliable barrier method until the next period. Clients should be advised to wait a minimum of 5 days after taking UPA-EC before starting/restarting suitable hormonal contraception and use barrier methods until then.

  Regular hormonal contraception may also reduce effectiveness of UPA as emergency contraception, so UPA may not be the EC of choice. For women requiring emergency contraception because of missed pills, please refer to advice in FSRH Guidance.
- **Future contraception** – barrier contraception (condoms) are recommended until the start of the next menstrual cycle. Discuss the need for reliable contraception for the future if necessary. Women should be advised to wait 5 days after taking UPA-EC before starting suitable hormonal contraception. Women should be made aware that they must use condoms reliably or abstain from sex during the 5 days waiting and then until their contraceptive method is effective. (See FSRH 2017 EC guidance, page viii and page 24).
- **Risk of STI** - EHC does not replace necessary precautions against sexually transmitted infections.
- **Drug Interactions**: See patient advice in drug interaction section.
- **Informing the GP** - Request the client's permission to inform their GP that a supply of EC has/has not been made.
- Explain the "Out of Hours" procedure.

Arrangements for Referral to Medical Advice

- Refer to Integrated Sexual Health services or GP as appropriate

Records

All details to be recorded on PharmOutcomes as detailed in the online tool and be retained according to local, legal and professional obligations.

Records should be kept that will demonstrate;

- Confirmation that consent has been obtained;
- Details of drug, batch number, dose supplied and date administered for audit purposes
- Confirmation that there are no contraindications; That side effects have been discussed; Support literature given (if applicable);
- Fraser guidance fulfilled for under 16.
- If individual is 16 years or over and not competent, action taken.
- Evidence of counselling and future contraception needs explored. Documentation of referral onward or advice sought.

Safeguarding Children

All staff should discuss any concerns that may undermine the safety of a vulnerable young person, including sexually active young people. Advice for Healthcare Professionals can be obtained by following the professional and training links through: www.safeguardingchildren.co.uk

For immediate safeguarding issue please contact Gateshead Children's Social Care team
During office hours (Monday - Thursday, 8:30am-5pm and Friday, 8:30am-4:30pm) please contact the Referral and Assessment Team on (0191) 433 2653 or email: R&ADuty@gateshead.gov.uk
On evenings and weekends please contact the Emergency Duty Team (EDT) on (0191) 477 0844 and ask for the EDT social worker

In an emergency, contact Gateshead Police on 999

Multi-agency Safeguarding Children Procedures (including referrals forms and details of referral pathway) can be found at: www.safeguardingchildren.co.uk

References

1. FSRH Guidance Emergency Contraception. (March 2017 updated Dec 2020). https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ Accessed 04/03/2021
2. British National Formulary. https://www.medicinescomplete.com Accessed 04/03/2021
3. Ulipristal SPC https://www.medicines.org.uk/emc Accessed 04/03/2021
4. DOH (2011). Quality criteria for young people friendly health services. https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services Accessed 04/03/2021
5. FSRH (2017). Quick Starting Contraception. https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/ Accessed 04/03/2021
6. Glasier AF, Cameron ST, Fine PM, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet 2010; 375:555–562
7. FRSH Guidance: Overweight, Obesity and Contraception (April 2019) https://www.fsrh.org/documents/fsrh-clinical-guideline-overweight-obesity-and-contraception/ Accessed 04/03/2021
8. FSRH Guideline: Combined Oral Contraception (Jan 2019, Amended Nov 2020) https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/ Accessed 04/03/2021
9. FSRH CEU Guidance: Recommended Actions after incorrect Use of Combined Hormonal Contraception (e.g. late or missed pills, ring and patch) (March 2020) https://www.fsrh.org/documents/interim-fsrh-guidance-on-incorrect-use-of-combined-hormonal/ Accessed 04/03/2021
10. FSRH Guideline: Combined Oral Contraception (Jan 2019, Amended Nov 2020) https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/ Accessed 4/3/2021
11. CPPE. Specimen Declaration of Competence for Pharmacy Emergency Contraception Service. https://www.cppe.ac.uk/services/docs/ec_wgll.pdf Accessed 04/03/2021.
12. NICE Medicine Practice Guidance Patient Group Directions MPG2 https://www.nice.org.uk/Guidance/MPG2 Accessed 04/03/2021

4. Characteristics of Healthcare Professional using this PGD

Only those pharmacists that have been specifically authorised by their clinical lead/supervisor/manager or by self-declaration may use this PGD for the indications defined within it. You may only supply or administer medicines under a PGD as named individuals.

Qualification/registration requirements

Currently registered with the General Pharmaceutical Council (GPhC) of Great Britain

Additional requirements (applies to all staff)

As detailed in the service specification:

- **Accreditation is via annual CPPE Declaration of Competence for Emergency Hormonal Contraception. Final declaration remains the professional responsibility of the practitioner.**
    - It is recommended that the signed Declaration of Competence (DoC) required for this service is equivalent to the standards detailed within CPPE module Emergency Contraception www.cppe.ac.uk/programmes/l/ehc-e-03
    - **Plus, practitioners MUST attend a local Gateshead workshop** (delivered by Consultant in Sexual Health) **or demonstrate the studying of the online update slides and videos. If you have studied the online update, this should also be reflected on within your DoC at CPPE**
      This covers local pathways and safeguarding arrangements. Date of attendance / studying of **online update** **MUST** be **within 2 years** of the consultation claim. Practitioners must take all practicable steps to attend / study these workshops or payments maybe withheld upon ongoing failure to do so.
- Practitioners must meet and evidence upon request declared competencies for the purposes of audit and quality checks.
- Providers must retain copies of their own or Staff's evidence of accreditation and training at the premises where they offer the Service and provide copies to the Council upon request. This remains an enrolled service. Ensure CPPE viewer is enabled to allow commissioners the option to audit competency status.
- The Provider will be required to comply with General Pharmaceutical Council Standards of Conduct, Ethics and Performance and demonstrate maintenance of knowledge, skills and competencies, with evidence of Continuing Professional Development, ideally via the professional registration and revalidation process on the General Pharmaceutical Council website www.mygphc.org/home
- Competency in the use of PGDs (see NICE competency framework for health professionals using patient group directions). https://www.nice.org.uk/guidance/mpg2/resources
- The Provider shall ensure that each practitioner ensures their skills and knowledge are kept up to date prior to supplying under the PGD. Each practitioner supplying under the PGD should sign the Authorisation section of each PGD and that they accept personal responsibility for working under them, understand the legal implications and work within the scope of the PGD.
- Each practitioner must sign and date the current PGD and locums should sign the PGD for each shop they work in.
- The Provider must ensure that supporting Pharmacy Staff are trained in dealing with Service Users in a patient-centred, user-friendly, confidential and non-judgmental manner when requesting EHC.
- Pharmacists must with appropriate underpinning knowledge to competently undertake the clinical assessment of patients leading to treatment according to the indications listed in the accompanying PGDs.
- Each pharmacy must have a Standard Operating Procedure in place which covers the supply of an Ulipristal 30mg tablet via this PGD.

Management & Monitoring of Patient Group Direction GCP 2021/02C

The supply of

ULIPRISTAL 30MG TABLET

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named accredited pharmacist.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by the registered Healthcare Professional it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD. Pharmacists who do not have a clinical lead available to authorise them, will be required to authorise themselves, i.e. have the relevant Declaration of Competence in place.
- By signing this document, the pharmacist confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Agreement by Pharmacist

I _____ (name of healthcare professional), consider that I am competent to supply oral emergency hormonal contraception (Ulipristal 30mg). I have completed the appropriate training, as recognised by Gateshead Council, which will allow me to provide this professional service for up to **two years** from the date of the last Gateshead Council accredited training session I attended.

I have read and understood the Patient Group Direction

Ulipristal 30mg tablet – Direction number: GCP 2021/ 02C

I agree to supply Ulipristal 30mg tablet in accordance with this PGD (GCP 2021/02C). I will maintain clinical records as defined by the PGD, PharmOutcomes and in line with recognised governance standards.

Signature of Healthcare Professional: - _____

Date signed: _____ GPhC Registration no.:_____

Full address: ……
……
……

Authorisation from Clinical Lead to use this PGD (where available/appropriate)**: -**

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Clinical Lead: _____

Signature of Clinical Lead: _____ Date signed: _____

PGD Valid from: 1st April 2021	Review Date: 1st February 2023	**Expiry Date: 31st March 2023**

APPENDIX 1: FRASER GUIDANCE (formerly known as GILLICK COMPETENCE)

In circumstances when it is believed that a client may be less than 16 years of age, the healthcare professional operating under this PGD will assess the client's 'Fraser Ruling' (formerly known as 'Gillick Competence'). Contraceptive advice and treatment can be offered to young people less than 16 years without parental consent provided that the health professional explored the following issues and has confirmed that the young person is able to meet all the Fraser criteria below.
The following protocol should be used to support explorative discussion with the client and to act as a record and assessment tool for the client's maturity.

Is the healthcare professional satisfied that:	**YES**	**NO**
The client understands the advice given?		
The client has been encouraged to involve her own parents or carers?		
You have adequately considered the possible effect on the physical or mental health of the young person should the advice or treatment to be withheld?		
The action is in the best interest of the young person?		

If the answer to any of these questions is no, then the patient is not Fraser competent and administration/supply must not be made.

The Sexual Offences legislation does not affect the duty of care and confidentiality of health professionals to young people under 16. Health professionals are not liable to prosecution when they are acting to protect a child or young person, for example, when providing contraception or sexual health advice to a child under 16. The right to confidential advice on contraception extends to all young people, including those under 13, but the duty of confidentiality is not absolute and the younger the person, the greater the concern should be about the possible existence of abuse or exploitation.

Comments by the Healthcare Professional operating under this PGD:
(if no comment than write ***'no comment'***)

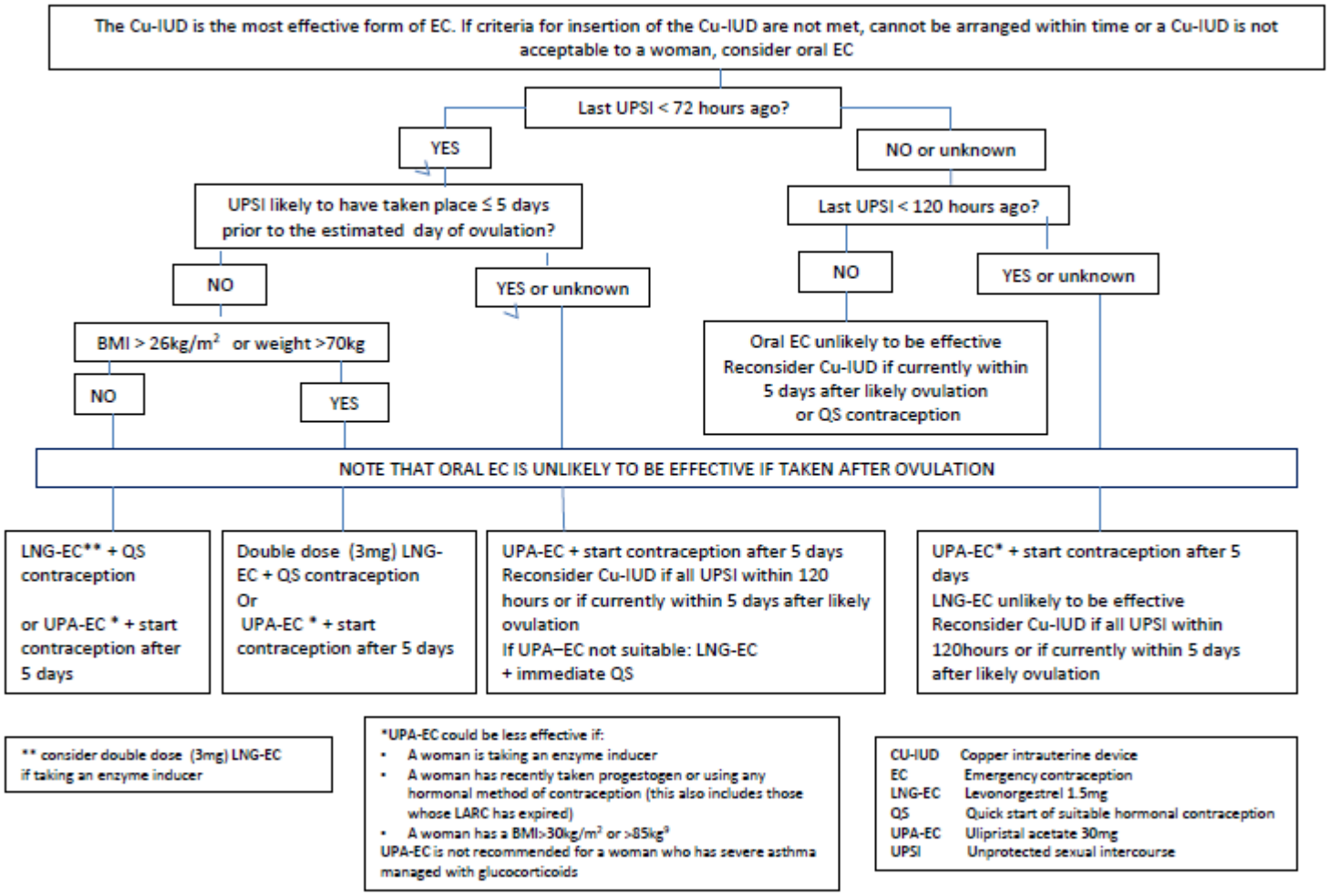
Client's name: ……....

Client's signature: …… Date: ……

Healthcare Professional's name: ……

Health Professional's signature: …… Date: ……

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



Adapted from Faculty of Sexual Health and Reproduction Healthcare 2017[1] and advice from Dr J Gallagher, Trust Associate Specialist Sexual Health Services, South Tyneside NHS Foundation Trust (updated Jan 2020)