North Yorkshire County Council

Health and Adult Services

Patient Group Direction (PGD) for the Supply / Administration of

ULIPRISTAL 30MG TABLET (ellaOne®) for Emergency Hormonal Contraception (EHC)

by Registered & Accredited Pharmacists to Individuals Accessing the NYCC EHC Service from Commissioned Community Pharmacies within North Yorkshire County Council (NYCC)

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

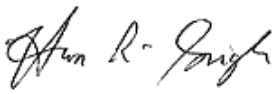
Direction Number: - **NYCC 2021/CP10**

Valid from: 1st December 2021

Review date: 31st October 2023

Expiry date: 31st January 2024

This patient group direction has been developed & produced by: -

Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (NHS North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		05/11/2021
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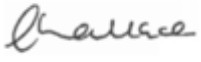
This PGD has been approved for use in North Yorkshire County Council by:

Title	Name	Signature	Date
Director of Public Health (North Yorkshire County Council Public Health)	**Louise Wallace** *(Authorising body Governance Authorisation)*		18/11/2021

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

- To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly 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).

Competent women aged 13-24 years old requesting EHC and one or more of the following criteria apply: -

1. Makes request for EHC within 120hrs of UPSI or within 120hrs of USPI due to potential failure of a contraceptive method listed in Table 1 and the client is either
   - aged 16 to 24 years (assess formerly if competence in doubt) **or**
   - aged 13, 14 or 15 years and considered to be Fraser competent by satisfying the assessment within the Fraser Guidance (see Appendix 1).

   Table 1- Possible failure/reduced efficacy of contraceptive methods include [1,2,3]: (Refer to current BNF)
   - Potential barrier method failure or regular non-hormonal contraception has been compromised or used incorrectly
   - 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 [2]
   - Risk of conception whilst advised to avoid pregnancy, such as following administration of cytotoxic agents or potentially teratogenic drugs.
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. (See Appendix 2).
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 [1]).
4. Is requesting EHC 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).
For further guidance on inclusion criteria see Appendix 2.
(Refer to the FRSH Emergency Contraception March 2017 (Amended Dec.2020) guidelines for additional information).

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.
- Females aged 12 years and under or females aged 25 years or over.
- Where consumption of the dose would be over 120 hours since this episode of UPSI.
- This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours.
- The client is not present to obtain the supply in person. (No third party supplies are permissible).
- Individuals 16 years of age and over and assessed as lacking capacity to consent.
- Female under 16 years old and assessed as lacking capacity to consent using Fraser Competence Guidelines (see Appendix 1).
- No menstrual period within the last 24 months.
- Relevant medical history is not provided by the client.
- Hormonal contraception used incorrectly e.g., missed pill; Depo Provera late by > 14 weeks from previous injection; Implant > 3 years use, (Please refer Appendix 2 and to section 4.3, FRSH 2017 EC guidance).
- Has taken progestogen containing drugs including LNG-EC within the previous 7 days.
- Where two previous episodes of UPSI have already been treated with a supply of levonorgestrel or ulipristal within this cycle.
- Post-natal clients presenting within 21 days after giving birth. (UPSI more than 21 days after delivery can lead to pregnancy).
- Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).
- Known or suspected 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) **
- Abnormal or unexplained vaginal bleeding; Severe hepatic impairment.
- Patients with severe asthma controlled by oral glucocorticoid.
- Taking interacting medicines (See BNF Appendix 1 for full list) either currently or within 28 days of completing treatment. (Please refer to Levonorgesterol (Levonelle) PGD for alternate EC treatment option).
- Those using liver enzyme-inducing drugs or herbal products (e.g., rifampicin, long term ritonavir, phenytoin, phenobarbital, carbamazepine, , , nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort) or within 4 weeks of stopping
- Galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption.
- Any contraindication to Ulipristal 30mg (ellaOne) **(see manufacturer's ellaOne SPC)**
- Known hypersensitivity to any ingredient, component or excipient of the tablet [4] (refer to SPC);

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.
- Ulipristal is ineffective if taken after ovulation.
- For clients **taking liver enzyme inducing drugs** e.g., carbamazepine, rifampicin, griseofulvin, efavirenz, (refer to BNF/SPC for full details), or who have stopped taking this medication within the last 28 days, refer to the Levonorgesterol (Levonelle One) PGD for possible treatment option. Where this is also unsuitable, then refer to YORSexualHealth https://yorsexualhealth.org.uk/ for Cu-IUD. They should be advised that a Cu-IUD is the only method of EC not affected by these drugs.[1]
- **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)
- Consider **child protection issues** in females aged 13-17 years and any safeguarding issues in those aged 18 years and over.

Continued on next page.

Cautions/Precautions - continued

- **Delay hormonal contraception** for 5 days after taking UPA-EC. The effectiveness of UPA-EC could be reduced if a woman takes progestogen in the 5 days after taking UPA-EC.
- Following a 5 day break upon restarting combined hormonal and progestogen-only contraceptive barrier methods additional precautions (barrier methods) required for 12 days for combined and parenteral progestogen-only hormonal contraceptives (14days for *Qlaira*®) and 7 days for oral progestogen-only contraceptives (this includes the 5 day before restarting contraception).
- Consider risks due to **ovulation timing**.
- When there is suspected **sexually transmitted infection** (STI), refer to YORSexualHealth services or their own GP.
- Body Mass Index (BMI) >26kg/m^2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC.
- 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.
- If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.
- If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy.
- If the individual has not yet reached menarche consider onward referral for further assessment or investigation.

Action to be taken if patient excluded

- Explain the reasons for exclusion to the individual and document in the consultation record.
- If consumption of the dose would be beyond 120 hours since this episode of UPSI, refer to YorSexualHealth, GP or A&E immediately for consideration of possible alternative prophylaxis (e.g. Cu-IUD).
- If excluded for any other reason, refer to YorSexualHealth (family planning), GP or A&E 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 YORSexualHealth 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 YORSexualHealth or GP.
- Record the decline/refusal in the clinical record and document all other actions taken.

2. Description of treatment

Name, strength & formulation of drug

Ulipristal 30mg tablet (as ellaOne® manufactured by HRA Pharma UK and Ireland Limited)

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/Supply

One single treatment dose. The client should preferably 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: - 2 separate episodes of UPSI in the same menstrual cycle
(Please note: If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal). If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel).

Follow up treatment/action

- **A pregnancy test is recommended in three weeks' time.**
- When there is suspected STI, signpost to YorSexualHealth 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 appropriately 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 CuIUD should be recommended for these women or LNG-EC.

  Examples of enzyme inducing drugs include: - carbamazepine, griseofulvin, modafinil, nelfinavir, nevirapine, oxcarbazepine, phenytoin, phenobarbitone, primidone, ritonavir, St John's Wort, topiramate, rifampicin and rifabutin, ritonavir, **but please refer to the current BNF Appendix 1 for a full list of drug interactions**.
- For the above patients where EC is considered necessary, then they should seek suitable healthcare provision immediately, e.g., YorSexualHealth, GP or A&E, 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 and manufacturers SPC for details of all interactions

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See manufacturers SPC (available at www.mediciness.org.uk) and current BNF for full details

- 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.
- The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.

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. [3]

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 (ellaOne®) 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.
- UPA-EC may be less effective in women with a BMI>30kg/m^2 or a weight >85kg.
- Have access to the current PGD, updated FSRH Emergency Contraception Guideline (March 2017); 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 YorSexualHealth (leaflets available),
- 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.
- Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g., shorter, or lighter than usual), or if using hormonal contraception which may affect bleeding pattern.

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):

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Advice to Patient (verbal or written) - continued

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 fetal abnormality, but every pregnancy has a chance of foetal abnormality. If UPA-EC has been taken in a cycle in which pregnancy is conceived, it should be reported to http://www.hra-pregnancy-registry.com/en/
- **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. there is no increased risk of ectopic pregnancy occurring if 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** – if the next period is delayed by >7days, consider pregnancy & seek pregnancy test. Pregnancy test in 3wks anyway.
- **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 HC. Woman wishing to start or continue HC 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 5days after taking UPA-EC before starting/restarting suitable HC & use barrier methods until then.

  Regular HC 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 Appendix 2 & FSRH.
- **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. In line with FSRH guidance women should be advised to wait 5 days after taking UPA-EC before starting suitable HC. 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 vii, viii and page24).
- **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 YorSexualHealthservice or GP as appropriate

Records

All details to be recorded on PharmOutcomes as detailed in the on line tool and be retained according to local, legal and professional obligations. All records should be clear, legible and contemporaneous.

Records should be kept that will demonstrate;

- Confirmation that consent has been obtained;
- Recorded that administered/supplied via PGD;
- 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);
- Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight
- Any known medication allergies
- Fraser guidance fulfilled for under 16. If not Fraser competent then record action taken including safeguarding input.
- If individual is 16 years or over and not competent, action taken.
- Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight
- Any known medication allergies
- Evidence of counselling and future contraception needs explored. Documentation of referral onward or advice sought.

Safeguarding Children & Adults

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

To report or discuss a safeguarding concern please contact NYCC Customer Contact Centre on 01609 780780
For adults the email is Social.care@northyorks.gov.uk (Out of hours number for emergency duty team is 01609 780780)
For children the email is children&families@northyorks.gov.uk

In an emergency, contact North Yorkshire 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

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2. Electronic British National Formulary (BNF) https://bnf.nice.org.uk/
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4. CPPE (2016). Specimen Declaration of Competence for Pharmacy Emergency Contraception Service. https://www.cppe.ac.uk/services/docs/ec_wgll.pdf. Accessed 23/05/19.
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7. FSRH (2017). Quick Starting Contraception. https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/ Accessed on 02/11/21
8. 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.
9. FSRH (April 2019). Clinical Guideline - Overweight, Obesity and Contraception. Available at https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/contraception-for-specific-populations/overweight-and-obesity
10. Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/
11. Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines

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)

- 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
- Pharmacist with appropriate underpinning knowledge to competently undertake the clinical assessment of patients leading to treatment according to the indications listed in this PGD.
- Meet the workforce provision of EHC requirements as set out in the NYCC Service Specification for the "Targeted Primary Care Sexual Health Service Provided in Community Pharmacies."
- Pharmacists to complete their Declaration of Competence Certificate (DOC) for EHC and any required training as part of the DOC as defined by the CPPE. Pharmacists should register their DOC on the CPPE website (https://www.cppe.ac.uk/services/declaration-of-competence).
- Each pharmacist delivering the service on behalf of the Provider must complete their Declaration of Competence Certificate (DOC) for EHC before they can provide this Service (a three month grace period is in place). The DOC must be renewed every three years. The Provider must inform the commissioner when this DOC has been completed and when subsequent re-accreditation has been completed. This should be done by enabling the CPPE viewer facility via the *Profile* section of the *My CPPE* page to allow access by the Commissioner
- To attend a one-off training session provided by YorSexual Health that will cover the local PGDs, Chlamydia screening, condom distribution, other sexual health services available locally and safeguarding. Pharmacists employed by the provider will attend a further training event if they, YorSexual Health or the Commissioner feel this would be useful to refresh knowledge.
- Accredited pharmacists will retain all training documentation.
- To have access to PharmOutcomes. Pharmacists must enable PharmOutcomes to access their CPPE record.
- The pharmacist must ensure that the pharmacy they are working in is an approved provider of EHC provision under PGD before making any supply under this PGD.
- If not already trained, pharmacists are encouraged to undertake the FSRH's online course on conducting a contraceptive choices consultation, https://www.fsrh.org/education-and-training/fsrh-contraceptive-counselling-online-course/
- By signing up to this PGD, the pharmacist accepts personal responsibility for working under it, understands the legal implications of doing so, and works within the scope of the PGD.
- It is the responsibility of the pharmacist to ensure that they have appropriate up to date knowledge of the medicine prior to its supply and to maintain this knowledge and keep up to date with relevant developments
- The Provider will be required to comply with GPhC Standards of Conduct, Ethics and Performance and demonstrate maintenance of knowledge, skills and competencies, with evidence of Continuing Professional Development, ideally via CPD entries on to the General Pharmaceutical Council Website www.uptodate.org.uk/home/welcome.shtml.
- Each pharmacy must have a Standard Operating Procedure in place covering the supply of Ulipristal 30mg tablet via this PGD.
- The Provider must ensure that supporting pharmacy staff are trained in dealing with patients in a patient-centred, user-friendly, confidential and non-judgmental manner when requesting EHC. Providers are expected to work towards implementing the Department of Health paper 'You're Welcome' Quality Standards. [5]
- Medicine counter staff must be trained to refer requests for EHC to the pharmacist or a suitable alternative provider if the pharmacist is not present.
- The pharmacist is required to maintain own level of updating and competence with evidence of continued professional development and adhere continued training requirements as deemed necessary by your organisation or the authorising body. (NB. If not already trained, pharmacists are encouraged to undertake the FSRH's online course on conducting a contraceptive choices consultation, available at https://www.fsrh.org/education-and-training/fsrh-contraceptive-counselling-online-course/).

Management & Monitoring of Patient Group Direction NYCC 2021/CP10

The Supply/Administration of

ULIPRISTAL 30MG TABLET (EllaOne®)

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 NYCC, which will allow me to provide this professional service for up to **three years** from the date of the last NYCC accredited training session I attended.

I have read and understood the Patient Group Direction

Ulipristal 30mg tablet (EllaOne®) – Direction number: NYCC 2021/CP10

I agree to supply Ulipristal 30mg tablet (EllaOne®) in accordance with this PGD (NYCC 2019/CP06). 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 December 2021	Review Date: - Oct. 23	**Expiry Date: - 31st January 2024**

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

ADVICE for PROFESSIONALS SUPPLYING ORAL EMERGENCY HORMONAL CONTRACEPTION (Ulipristal 30mg (ellaOne))

Failure rate

ellaOne® does not have as high a success rate as established methods of regular contraception, e.g. the pill or barrier methods, therefore the patient should not expect a 100% success rate. Amongst other factors, the success of ulipristal 30mg in preventing pregnancy depends upon how soon the dose is taken after unprotected sexual intercourse (UPSI).

- There is no significant reduction in effectiveness observed with increasing time between UPSI and UPA-EC (up to 120hours) (page 12, FSRH).
- 1-2% of all women who take UPA-EC after UPSI will become pregnant.

Verbal advice on nausea and vomiting

The patient must be advised that the tablet may cause nausea and vomiting. If vomiting occurs within three hours of taking the dose, further advice must be sought immediately from a health professional. Taking with or after food can sometimes reduce side effects.

Guidance for a lost or vomited tablet: If the tablet has been lost, a further tablet may be supplied if this is considered appropriate. If the tablet is vomited within 3 hours of ingestion, the dose may be repeated provided that the dose is still within 120 hours of the UPSI being treated. Anti-emetics may be advised. If the new dose would be later than 120 hours after the episode of UPSI in that cycle, referral for an IUCD may be indicated and the tablet ***should not*** be issued.

Supplementary Patient Information

The following advice leaflets are available for the patient:

- Manufacturer's patient information leaflet - essential
- Leaflet on methods of contraception and websites www.brook.org.uk and www.fpa.org.uk - advisable
- Website advise on local sexual health Services (YorSexualHealth) - advisable
- Leaflet on Out of Hours - advisable

Follow-up Advice

Menstrual periods - If menstrual periods are delayed by more than 7 days or abnormal bleeding occurs or pregnancy is suspected the possibility of pregnancy should be considered.

Abnormal abdominal pain or heavy bleeding should be referred.

Ectopic pregnancy can occur should the prophylaxis fail – seek pregnancy test if pregnancy suspected.

Foetal effects – There is no evidence that this method of contraception has any teratogenic effects (were conception to take place), however, pregnancy has a high overall chance of foetal abnormality (1 in 50).

Effective contraception - A visit to a GP or clinic about three weeks after completing a course of oral EHC should be recommended if there are any concerns of a possible pregnancy. It may be advisable for the client to seek advice earlier about ongoing contraception.

Adverse Drug Reporting (ADRs)

All ADRs, even if it is well recognised, should be reported using the CSM Yellow Card Scheme, either by a doctor, pharmacist, nurse or patient. For supporting information see British National Formulary (BNF), which also contains yellow reporting cards. The client may need to be referred to their doctor.

Contraception

The requirement for emergency contraception (EC) should be assessed if there has been recent UPSI. If EC is indicated, the copper intrauterine device (Cu-IUD) should be considered first, as it is the most effective method of EC and provides ongoing contraception. After levonorgestrel EC (LNG-EC), HC can be quick started immediately. However, after ulipristal acetate EC (UPA-EC), HC should not be started for 120 hours. **This is a change to previous Faculty of Sexual & Reproductive Healthcare (FSRH) quick starting contraception guidance.**

- Emergency contraceptives are less effective than established regular contraceptive methods (e.g. pill or barrier methods) and should not be used as an alternative to regular contraception.

- After taking oral EC there is still a pregnancy risk if there is a further UPSI and ovulation occurs later in the same cycle.
- Additional contraceptive precautions (barrier or abstinence) are required until the quick started contraceptive method becomes effective.
- Women should wait 5 days after taking UPA-EC before starting suitable contraception. (See table 2 & 3).

Table 2: When to start hormonal contraception after UPA-EC

Start hormonal contraception >120 hours after UPA-EC	
If UPA taken on…	120 hours later falls on…
Sunday	Friday
Monday	Saturday
Tuesday	Sunday
Wednesday	Monday
Thursday	Tuesday
Friday	Wednesday
Saturday	Thursday

Table 3: Time to contraceptive effectiveness when starting 120 hours after UPA-EC

Contraceptive Method	**Requirement for additional contraception after starting method**
Combined oral contraceptive pill*	7 days
Combined vaginal ring/transdermal patch	7 days
Progestogen-only pill (traditional/desogestrel)	2 days
Progestogen-only implant or injectable	7 days

*Except Qlaira which requires 9 days of additional contraceptive precautions.

Practicing Safer Sex

Neither oral EHC nor oral contraceptive pills provide protection against sexually transmitted infections.

Audit trail

The health professional must keep a record of the consultation and outcome **(PharmOutcomes)** for an agreed period according to local, legal and professional obligations. It is also recommended that computerised patients medication records be kept where possible.

Informing the Patient's GP

It is not essential that the supply of oral EHC is reported to the patient's GP, but the patient should be encouraged to give permission to inform her own GP of this supply **(see Appendix 3)** and to let the health practitioners know of the supply when next attending for contraception.

Missed Pills OR Accidental Lengthening of the Pill Free Interval
(Please see LNG-EHC PGD & new FSRH (2017) EC guidance)

If UPA-EC is taken, its effectiveness for EC could be reduced if progestogen is taken in the following 5 days. Quick start of suitable HC should therefore be delayed for 5 days (120 hours) after UPA-EC. This ensures that the UPA-EC is as effective as possible in preventing pregnancy resulting from the episode(s) of UPSI for which it was taken. Importantly, there is a risk of pregnancy if there is further UPSI before ongoing contraception is started and becomes effective. The woman should be advised to use additional contraception (barrier or abstinence) during the 5 days waiting and then until the chosen contraception becomes effective.

In applying the 'missed pill rules,' clinicians must remember that there comes a point when a woman has missed so many pills that she must be viewed as having stopped taking the pill. The Faculty of Sexual and Reproductive Healthcare considers that if a woman has missed more than seven consecutive pills, then she has stopped using COC, and the 'missed pill rules' cannot be applied.

a) Combined oral contraceptive pills (COC).
The critical time for loss of contraceptive protection is when a pill is omitted at the beginning or end of a cycle (which lengthens the pill-free interval).
UPA-EC is not recommended if a CHC has been taken in the 7 days prior to EC, as the effectiveness of UPA-EC is reduced. Consider use of LNG-EC (Refer to LNG-EC PGD).

CHC containing cyproterone acetate should not be quick started unless pregnancy can be reasonably excluded.

Note: The Faculty of Sexual and Reproductive Healthcare (FSRH) offers updated advice for what EC is indicated following potential failure of hormonal and intrauterine methods of contraception (see Table1 page 5 of FSRH guidance: https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/).

b) Oral progestogen only contraceptive pills
UPA-EC is not recommended if a POP has been taken in the 7 days prior to EC, as the effectiveness of UPA-EC is reduced. Consider use of LNG-EC (Refer to LNG-EC PGD).

c) Delayed application or detached patch
If a patch is partly detached for less than 24 hours, reapply to the same site or replace with a new patch immediately; no additional contraception is needed and the next patch should be applied on the usual 'change day'.

If the patch remains detached for more than 24 hours or if the user is not aware when the patch became detached , then stop the current contraceptive cycle and start a new cycle by applying a new patch, giving a new 'day 1', an additional non-hormonal contraceptive must be used concurrently for the next 7 days of the new cycle.

The Effect of Weight/BMI on the Effectiveness of EC
It is recommended that either UPA-EC or a double dose (3 mg) of LNG-EC is given if a woman has a BMI >25 kg/m2 or weight >70 kg. It is unknown which is more effective.

Advice after EHC
CHC, IMP and DMPA commenced 5 days after administration of UPA-EC will be effective 7 days after starting and POP 2 days after starting (see Table 4).

Table 4: Time to contraceptive effectiveness when starting 120 hours after UPA-EC

Contraceptive method (start >120 hours after UPA-EC)	**Requirement for additional contraception after starting method (days)**
Combined oral contraceptive pill (except Qlaira®)	7
Qlaira combined oral contraceptive pill	9
Combined vaginal ring/transdermal patch	7
Progestogen-only pill (traditional/desogestrel)	2
Progestogen-only implant or injectable	7

(FSRH (2017) Guideline - Quick Starting Contraception)

Appendix 3

TEMPLATE LETTER

PRIVATE AND CONFIDENTIAL

Date: *Pharmacy stamp:*

Dear Dr . . . . . .

Re: Client's name . . . . . .

Client's date of birth . . . . . .

Client's address . . . . . .

. . . . . .

. . . . . .

A. I am writing to inform you that the above patient was supplied with a course of Ulipristal emergency hormonal contraception on ……..

B. I am writing to inform you that the above patient requested a course of Ulipristal emergency hormonal contraception on ……. I was unable to supply the medication because

……

……

……

……
and I would therefore be grateful if you could see this patient as soon as possible.

Yours sincerely

Signed……

Name……..

GPhC Registration number…….. …….