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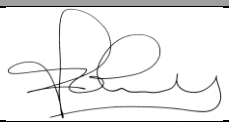
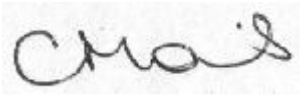
Amendment Dates:	**Page(s)**	**Brief Description**
February 2018		New PGD

NB: Always access the electronic version of this PGD to ensure that you are using the most up to date version.

The practitioner MUST be authorised by name, under the current version of this PGD before working according to it.

Patient Group Direction for: Ulipristal acetate 30 mg

Approved By

NHS Telford and Wrekin Clinical Commissioning Group	Name	Signature
Clinical Chair	Dr Jo Leahy	
Head of Medicines Management	Jacqui Seaton	
Executive Lead for Quality, Nursing and Safety	Christine Morris	

Date of patient group direction approved	May 2018
Date this patient group direction becomes due for review	May 2020 or in response to new local/national guidelines

Specialist Advice	Organisation	Signature	Date
Dr Arabinda Kundu – Consultant in Sexual and Reproductive Health	SSSFT		25/04/2018

STAFF CHARACTERISTICS

- Working for providers of NHS Pharmaceutical Services within NHS Telford and Wrekin CCG

- GPhC registered Pharmacist deemed competent in the administration and supply of post-coital contraception – ulipristal 30mg for post-coital contraception purposes. The pharmacist will have due regard for the General Pharmaceutical Council Standards of conduct, ethics and performance.

Specialist competencies or qualifications:

- The healthcare professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions

- The clinical manager or service lead has evidence that the registered healthcare professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.

- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.

- Completion of current online EHC CPPE (learning programme and assessment)

- Completion of CPPE safeguarding children and vulnerable adults level 1, Combating CSE and NHS Spotting the signs of child sexual exploitation (e-assessment learning)

- The clinical manager or service lead has proof of training by the healthcare professional on the legal aspects of supply or administration of medicines under a Patient Group Direction

- The clinical manager or service lead has assessed the competency of the healthcare professional to work to a Patient Group Direction at least every 2 years (for pharmacists this will usually be in the form of training and a self-declaration of competency) The NICE competency framework for people authorising PGDs and the NICE competency framework for healthcare professionals using Patient Group Directions[4] should be used to support this assessment.

- Must have access to all relevant sources of information e.g. information issued by the Department of Health (DH), British National Formulary (BNF), Summary of Product Characteristics (SPC), and any clinical guidelines concerning medicine(s) within this Patient Group Direction (PGD).

- All staff operating within the PGD must update their knowledge and skills in this area of practice with particular reference to changes and national directives

- All staff operating within the PGD must be Competent to follow and administer patient group direction - showing clear understanding of indications for treatment, exclusions from treatment (and subsequent action to be taken) and the treatment itself.

- All staff operating within the PGD should have a clear understanding of the drug administered including side effects and contraindications

- The registered healthcare practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR MANAGER UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT
PGDs DO NOT REMOVE INHERANT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY
Always ensure that you are using the most up to date version of this PGD.

Patient Group Direction for supply of ulipristal acetate 30mg (Emergency Hormonal Contraception) by registered pharmacists	
CLINICAL CONDITION	
Clinical need addressed	Clients requesting emergency contraception within 120 hours of unprotected sexual intercourse (UPSI) for the prevention of unwanted pregnancy where Cu-IUD is declined by the client or where unable to get access for this provision. **NB** Clients should always be advised that the Cu-IUD is the most effective method of emergency contraception. If the client is referred on for a Cu-IUD, oral emergency contraception should be given at the time of the referral in case the Cu-IUD cannot be fitted or the client changes their mind.
Inclusion Criteria	• All clients aged 13 years to 25 years of age presenting for emergency contraception between **72 and 120** hours of unprotected sexual intercourse, or failure of other method of contraception and the patient has declined Intra-uterine Contraceptive Device (copper) or where unable to get access for this provision • All clients 13 years to 25 years of age presenting for EHC where UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation (usually days 11-15 of cycle). (These clients would be excluded under the levonorgestrel PGD) • All clients 13 years to 25 years of age presenting for EHC within 120 hours of USPI who weigh more than 70kg or have a BMI >26kg/m^2 (these clients would be excluded under the levonorgestrel PGD) • If client has received ulipristal Acetate 30mg under this PGD, but has vomited within 3 hours of the dose (provided still within 120 hours of sexual intercourse) NB: • **If the patient is aged 16 or under, they must be assessed for competence using the Fraser Guidelines. (Appendix 1)** • **The client must be competent to give informed consent to treatment** For missed pills see current guidance from Faculty of Family Planning and Reproductive Healthcare Clinical Effectiveness Unit. https://www.fsrh.org/documents/cec-ceu-statement-missed-pills-may-2011/
Exclusion criteria (for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)	• If unprotected sexual intercourse (UPSI) occurred more than 120 hours previously. • Pregnancy or suspected pregnancy (If a woman's menstrual period is late or in case of symptoms of pregnancy, pregnancy should be excluded before ulipristal 30mg is supplied) • Breast feeding (ulipristal acetate is excreted in breast milk. The effect on newborn/infants has not been studied. A risk to the breastfed child cannot be excluded.) • Clients less than 13 years of age • Clients aged 26 years and over • Individuals under 16 years of age and assessed as not competent to consent to treatment using Fraser guidelines

	• Individuals not consenting to treatment or deemed not competent to consent to treatment • Previous supply of ulipristal in the same menstrual cycle (unless the client has vomited within 3 hours of an initial dose) • Previous supply of levonorgestrel 1.5mg in the same menstrual cycle • Hypersensitivity to the active substance or to any of the excipients • Client's last period was late or last period was unusual (recommend a pregnancy test) • Women with severe asthma insufficiently controlled by oral glucocorticoids • Severe hepatic impairment • Unexplained vaginal bleeding • Breast cancer • Severe malabsorption syndrome such as Crohn's disease • Women with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption • If client is taking any liver enzyme inducing drugs – Consult current BNF / Current faculty of family planning and reproductive healthcare clinical effectiveness unit guidance. Liver enzyme inducers may reduce plasma concentrations of ulipristal acetate reducing its efficacy. The reduction in efficacy may occur even if the woman has stopped taking an enzyme inducer within the last 2-3 weeks. (See levonorgestrel PGD if applicable) • Drugs suspected of having the capacity to reduce the efficacy of ulipristal 30mg - rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoine, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort/Hypericum perforatum, long term use of ritonavir • Women taking medicinal products that increase gastric pH (e.g. proton pump inhibitors, antacids, and H2 receptor antagonists). These preparations may result in a decrease in ulipristal acetate efficacy
Supply To young persons	• If a young person (aged <16 years) requests Emergency Contraception, then they must be assessed for competency. If they are deemed as being 'Fraser Competent' then a supply can be made, but this must be documented in the records • Pharmacists must use their professional judgement when considering 'Safeguarding' issues related to sexual activity in young persons. **. If there are any concerns about a child being abused Pharmacists must contact Family Connect (01952 385385 / after 5pm and on weekends contact the emergency duty team 01952 676500) – records details of the referral including the names of all individuals you spoke to** • If a child under 13 years requests Emergency Contraception, and there is a reasonable concern that sexual activity has taken place, the pharmacist should always contact the local Child Protection Lead, and there must always be a presumption that the case will be referred to the Children's Social Care Services in the area where the child lives
Management of excluded patients	• Explain the reason for exclusion and document all actions taken within clients Pharmoutcomes record. • Refer all clients with contra-indications to their GP or the Sexual Health

	Clinic (Tel 0300 123 0994) for further consultation • For clients who are excluded because they are taking liver enzyme inducing drugs refer to Levonorgestral PGD if applicable or refer to sexual health services (0300 123 0994) or the clients GP • If more than 120 hours have elapsed, the IUD is the appropriate method of contraception and should be discussed with the client before referral to the Sexual Health Clinic (Tel 0300 123 0994 details of service opening times can be found on their website openclinic.org.uk) or the client's GP. (NB. Not all GP's will fit IUDs). A current FPA leaflet should be given • If the client is aged under 13 years, the pharmacist should contact the local Safeguarding Team – Family Connect 01952 385385. With the clients consent the Sexual Health services should be contacted - Clinic (Tel 0300 123 0994) to inform them of the client's attendance such that the consultation can be prioritised. Consent must be given by the client to do this • Clients aged 26 years and over should be advised that they can purchase EHC or refer them to the sexual health services/their GP
Action for patients not wishing to receive care under this PGD	• The patient should be advised of the risks of not receiving the supply of **ulipristal acetate 30 mg** • Refer client to the GP or sexual health service doctor • If the client requests an emergency Cu-IUD refer to Sexual Health Clinic (Tel 0300 123 0994 details of service opening times can be found on their website openclinic.org.uk) . Oral emergency contraception, if appropriate, should still be given at the time of the referral in case the Cu-IUD cannot be fitted or the client changes their mind. • Client should receive advice regarding future contraception • Details of consultation and referral must be recorded within Pharmoutcomes client record. Notes should clearly document noncompliance with the PGD
Treatment and drug details	
Name form and strength of medicine	**Ulipristal Acetate 30 milligrams (UPA)**
Legal classification	• P – Pharmacy only medicine.
Black triangle warning Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).	None
Method of obtaining supplies	• From licensed and authorised supplier • From community pharmacies
Site for treatment	• Designated clinic sites / Community pharmacies
Route / Method	• Oral route only
Dose	• One tablet (30mg ulipristal acetate) to be taken as soon as possible between 72 and 120 hours after unprotected sexual intercourse or contraceptive failure. • If vomiting occurs within 3 hours of ulipristal 30mg intake, the efficacy

	of the treatment may be reduced and the dose should therefore be repeated. Ulipristal 30mg can be taken at any moment during the menstrual cycle. The tablet can be taken with or without food. (Please see notes below in caution/ need for further advice) **Repeat supply within the same menstrual cycle is NOT permitted within this PGD**
Number of times treatment may be administered or supplied	One single dose per episode (see notes above regarding vomiting) Repeated administration of ulipristal 30mg ® within the same menstrual cycle is not advisable. (Unless vomiting has occurred within 3 hours of taking the initial emergency dose). Further supplies in the same menstrual cycle are not permitted under this PGD – Refer to GP/Sexual Health Services
Quantity to be supplied or administered	**One tablet –** 30 milligrams ulipristal acetate **Medication should be issued directly to client to be taken immediately**
Caution / need for further advice	Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse earlier in the same menstrual cycle, conception may have occurred. Treatment with ulipristal 30mg 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. **Clients for whom ovulation has already occurred within the current cycle** Women should be advised that oral emergency contraception administered after ovulation is **unlikely to be effective**. If the client's ovulation date cannot be determined, or if there is any likelihood that ovulation has already occurred supply of oral emergency hormonal contraception can only be made if the pharmacist deems that it is in the best interests of the client to receive a supply, and the client is specifically advised that post ovulation, oral emergency hormonal contraception may not be effective.
Side effects *Full details of side effects are available in the SPC.* *www.medicines.org.uk* *And* ***Current BNF http://bnf.org/bnf*** *Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk*	**Common / Very Common side effects**: **(Very common (≥ 1/10), Common (≥ 1/100 to <1/10))** **Gastrointestinal** Very Common: Abdominal pain Common: Nausea, Vomiting, Dyspepsia **Infections** Common: The following infections have been reported (nasopharyngitis, urinary tract infection, fungal infection, influenza, vaginitis bacterial, kidney infection, hordoleum, conjunctivitis infective, pelvic inflammatory disease)

	Psychiatric disorders Common: Mood disorders **Nervous System Disorders** Common: Headache, dizziness **Musculoskeletal and connective tissue disorders** Common: Muscle spasms, back pain **Reproductive system and breast disorders** Common: Dysmenorrhea, menorrhagia, metrorrhagia **General disorders** Common: Fatigue Use the Yellow Card System to report adverse drug reactions directly to the MHRA. Yellow Cards and guidance are available at the back of the BNF. http://yellowcard.mhra.gov.uk/
Drug Interactions	CYP3A4 inducers (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, ritonavir, St John's wort/Hypericum perforatum) may reduce plasma concentrations of ulipristal acetate and may result in decrease in efficacy. Concomitant use is therefore not recommended. Enzyme induction wears off slowly and effects on the plasma concentrations of ulipristal acetate may occur even if a woman has stopped taking an enzyme inducer within the last 2 – 3 weeks. Concomitant administration of medicinal products that increase gastric pH (e.g. proton pump inhibitors, antacids and H2-receptor antagonists) may reduce plasma concentrations of ulipristal acetate and may result in decrease in efficacy. Concomitant use is therefore not recommended. Potent CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, telithromycin, clarithromycin, nefazodone) may increase exposure to ulipristal acetate. The clinical relevance of this interaction is unknown. • Potential for ulipristal acetate to affect other medicinal products: Because ulipristal acetate binds the progesterone receptor with high affinity, it may interfere with the action of progestogen-containing medicinal products: - Contraceptive action of combined hormonal contraceptives and progestogen-only contraception may be reduced (see advice to patient below) - Concomitant use of ulipristal acetate and emergency contraception containing levonorgestrel is not recommended.
Additional Information	• Children and adolescents; safety and efficacy of ulipristal 30mg ® has only been established in women 18 years and older. Supply to women younger than 18 years of age is **not** contraindicated. • Concomitant use with an emergency contraceptive containing levonorgestrel is not recommended • Emergency contraception with ulipristal 30mg ® should not be used as a regular form of contraception. It must never replace a regular contraceptive method.

	• It is recommended that subsequent acts of intercourse be protected by a reliable barrier method until the next menstrual period starts • Emergency contraception with ulipristal 30mg ® does not prevent pregnancy in every case. In case of doubt, (delay of period by more than 7 days, abnormal bleeding at the expected date of menses, or symptoms of pregnancy) then the patient should be advised to do a pregnancy test. If this is positive, medical advice must be sought • If pregnancy occurs after treatment with ulipristal 30mg, the possibility of ectopic pregnancy should be investigated • After ulipristal 30mg ® intake menstrual periods can sometimes occur earlier or later than expected by a few days. In approximately 6% of the women, menstrual periods occurred more than 7 days earlier than expected. In approximately 20% of the women a delay of more than 7 days occurred, and in 5.1% the delay was greater than 20 days
Advice to Patient	**The pharmacist should ensure the client gives consent before issuing ulipristal 30mg emergency contraception.** Patient Information Leaflets should be highlighted and given to all women supplied with ulipristal 30mg emergency contraception. The following points should be discussed with the client: • How the medication works, benefits of treatment and how it should be taken • Possible adverse effects • Advise Failure rate • Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 120 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with ulipristal 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 • Women should be advised that oral emergency contraception administered after ovulation is unlikely to be effective • If they vomit or have severe diarrhoea within 3 hours of taking ulipristal 30mg they should be advised to return to the pharmacy or visit their GP or Sexual Health Clinic. If the replacement dose would be later than 120 hours after unprotected intercourse, referral for a Cu-IUD should be advised, further supply should not be considered. • Changes to menstrual cycle (period may be early or late but most will have their next period within 7 days of the expected time) • Clients who receive ulipristal Acetate 30mg as an emergency contraception should be advised to have a pregnancy test within 3 weeks of taking ulipristal Acetate 30mg or if the next period is more than 7 days late or abnormal in anyway, they should go to their GP or Sexual Health clinic to exclude pregnancy. As with any pregnancy, the possibility of an ectopic pregnancy should be considered. It is important to know that the occurrence of uterine bleeding does not rule out ectopic pregnancy.

	• Discuss that ulipristal Acetate 30mg only provides contraception for the recent episode not for any other events that may occur in the future • Clients who receive ulipristal acetate 30mg as an emergency contraception should be advised to visit their GP or Sexual Health clinic to discuss on going contraception. (see notes below) • After using emergency contraception, it is recommended that subsequent acts of intercourse be protected by a reliable barrier method until the next menstrual period starts. (see notes below) • Ulipristal Acetate may have minor or moderate influence on the ability to drive or use machinery; mild to moderate dizziness is common, blurred vision is uncommon. The patient should be informed not to drive or use machines if they are experiencing such symptoms. • Discuss sexually transmitted infections and offer advice on screening and encourage condom use. • Women taking liver enzyme inducing drugs should be advised not to use ulipristal Acetate 30mg during or within 28 days of stopping treatment • Provide local guide to Sexual Health services **<u>Contraception after taking ulipristal 30mg</u>** Although the use of ulipristal 30mg does not contraindicate the continued use of regular hormonal contraception, ulipristal 30mg may reduce its contraceptive action. Therefore, if a woman wishes continue using hormonal contraception, she can do so after using ulipristal 30mg, however, she should be advised to use a reliable barrier method until the next menstrual period. Women who wish to quick start contraception after taking ulipristal 30mg must be advised to wait for 5 days before starting contraception.
Follow up	Vomiting within 3 hours of taking dose (See Dosage guidance) It is important to advise the client to return for a pregnancy test if the next menses is missed/lighter or more than 7 days late. If pregnancy occurs after treatment with ulipristal 30mg, the possibility of ectopic pregnancy should be investigated.
Suspected adverse reactions	Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations. All adverse reactions should be reported to the MHRA Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk
Error reporting	Any incidents or near miss issues must be reported via the organisation's internal reporting system.

RECORD KEEPING	
Documentation needed / treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	In discussion with the client enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation • Patient's name, address, date of birth • Record of informed consent (record Fraser competency assessment where applicable) • Inclusion or exclusion from PGD • Date of supply • Reason for attendance • Relevant past and present medical history, including drug history • Any known allergy • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the terms of the marketing authorisation • If individual is under 13 years of age record action taken • Informed verbal consent should be obtained (for clients aged under 16 years, Fraser guidelines should be followed) • Record Name (brand)/ Manufacturer / batch number / expiry date • Quantity supplied • Any other relevant information that was provided to the individual • Details of staff who supplied (sign and print name) • Details of any adverse drug reactions, and action taken • Reconciliation – stock balances should be reconcilable with receipts, administration, records and disposal on a patient by patient basis When the pharmacist has confirmed supply is appropriate the client must sign the treatment consent form before taking ulipristal. If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given.

Register of practitioners qualified to administer and / or supply **Ulipristal Acetate 30 mg** under this Patient Group Direction	
Name of clinical manager / Lead	
Signature of clinical manager / Lead	Date:
A copy of this page should be retained by the authorising manager for 2 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

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

- **PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**.
- It is the responsibility of each professional to practice only within the bounds of their own competence.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

Healthcare professionals working under a PGD must have received appropriate training and been assessed as competent to administer/supply the medicine referred to in the PGD. The clinical lead should review competency of authorised practitioner/s at least annually. Training certificates must be available for inspection.

Authorisation to use this PGD does not remove inherent professional responsibility and accountability

A copy of this authorisation form must be printed off, signed and dated by the healthcare professional authorised to use this PGD. This should be retained by the service provider and readily available for inspection).

REFERENCES	
	Current Edition BNF 74
	Product SPC – ellaOne ® (ulipristal 30mg) www.medicines.org.uk (last accessed 25.1.2017)
	Faculty of Sexual and Reproductive Healthcare Emergency Contraception (March 2017 updated Dec 17) https://www.fsrh.org/documents/ceu-clinical-guidance-emergency-contraception-march-2017/
	Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit CEU Statement (May 2011) Missed Pill Recommendations http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf
	Faculty of Sexual and Reproductive Healthcare (2017) Drug interactions with hormonal contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/

Appendix 1

The Fraser Guidelines

Please use this as a checklist for all clients aged 16 and under.

- The young person understands the advice and has sufficient maturity to understand what is involved.
- That the doctor/nurse could not persuade the young person to inform their parents, nor allow the doctor/nurse to inform them.
- That the young person would be very likely to begin or continue having sexual intercourse with or without contraceptive treatment.
- That without contraceptive advice or treatment, the young person's physical or mental health would suffer.
- That it would be in the young person's best interest to give such advice or treatment without parental consent.
- Under 16s have a right to confidentiality whether asking for contraceptive advice or any medical treatment.

(Family Planning Association Fact-sheet No 12, 1997)