Patient Group Direction for the supply of ulipristal acetate 30 mg emergency contraception

Title of patient group direction	The administration or supply of ulipristal acetate for emergency contraception
Approved at	NMP/PGD Group
PGD approved / valid from	March 2018
Review date	December 2020
Expiry date	March 2021
Clinical area(s) where PGD applies	Sexual heath and HIV outreach services within contractive and sexual health clinics, and in sexual health outreach services/locations
Identified Lead for monitoring / review and contact details	Wendy Billsborough

CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Changes to exclusions made in line with new FSRH emergency contraception guidance(3/2017) and UKMEC(2016): The guidance included in this PGD may not match that in the manufacturer's Summary of Product Characteristics but is supported by the Faculty of Sexual and Reproductive Healthcare (FSRH) clinical guidance. This was agreed by the PGD group in November 2014

List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	Wendy Billsborough – Advanced Nurse Specialist. Dr Frances Baker – Speciality Doctor Alison Chorlton – Lead Nurse Sexual Health Dr Ian Fairley, Clinical Director Lead Carolyn Boardall, Directorate Pharmacist

CLINICAL CONDITION	
Condition	Postcoital emergency contraception
Inclusion criteria	• See FSRH Decisional algorithm - FSRH Guideline Emergency Contraception (2017) • Considered as first-line oral EC when UPSI is likely to have taken place during the 5 days prior to ovulation. • Any woman requesting emergency contraception within 120 hours of unprotected sexual intercourse (UPSI) or contraceptive failure who has no contraindications. • UPA may be used more than once in a cycle • UPA may be given for UPSI even if there has been an earlier episode outside the treatment window (>120 hours ago) where EC was or wasn't given • A repeat dose of UPA may be supplied if the first dose of UPA has been vomited within 3 hours providing the new dose is still within 120 hours of UPSI
Exclusion criteria	**Personal Characteristics & Reproductive History:** • Child 12 years of age or under • Child under 16 years not considered competent under Fraser guidelines • Known pregnancy (NB a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period) • More than 120 hours since this episode of UPSI • Progestogens including Levonorgestrel EC taken within the previous 7 days • Less than 21 days following childbirth • Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease • Breastfeeding is not recommended for 7 days

	following ingestion (see Advice section) • Known allergy to the active ingredient ulipristal acetate or any excipients. • Unacceptable to patient to delay starting hormonal contraception for 5 days **Other Conditions:** • Acute porphyria • Severe asthma controlled with oral steroids • Lactose and galactose intolerance • Lapp lactase deficiency or glucose-galactose malabsorption • Patient wishes to see a doctor **Interacting medicines – see current BNF for interactions:** • Interacting medicines- see current British National Formulary for interactions. This includes the use of enzyme inducers in the previous 4 weeks and some over the counter medicines for indigestion or heartburn and herbal preparations including St John's Wort **Cautions:** • Breastfeeding is not recommended for 7 days following ingestion (see Advice section) • Inflammatory bowel disease (including Crohn's and ulcerative colitis) - oral EC may be less reliable if there is significant malabsorption
Action if excluded	• Refer to appropriate doctor/independent nurse prescriber, or GP if more appropriate, in an outreach setting • Discuss/offer alternative method of emergency contraception if appropriate • Document action taken in patient's records
Action for patients not wishing to receive care under the PGD	• Record the refusal in the clinical record • Refer to appropriate doctor/independent nurse prescriber if agreed with client

DESCRIPTION OF TREATMENT			
Name of Medicine	Ulipristal acetate 30mg		
Legal Classification	Prescription only medicine (POM)		
Licensing information	Yes. Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). • UPA may be used more than once in a cycle • UPA may be given for UPSI even if there has been an earlier episode outside the treatment window (>120 hours ago)		
	Is the medicine licensed for the intended use?	**YES**	
	Does it have a black triangle status?		**NO**
Form	Tablet		
Strength	Each tablet contains 30 mg ulipristal acetate		
Dose	Single 30mg dose		
Frequency	30mg (1 tablet) to be taken as a single dose within 120 hours of UPSI NB: If vomiting occurs within 3 hours of taking ulipristal acetate another tablet should be taken if it is still within 120 hours of UPSI Can be repeated within the same menstrual cycle if required		

Route	Oral
Total Treatment Quantity	Single emergency treatment dose A second treatment may be supplied if the first tablet has been vomited within 3 hours provided the new dose is still within 120 hours of UPSI
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	• Check any medicines in appendix 1 of the British National Formulary under ulipristal or UpToDate – Drug Interactions via Staff Room • Avoid use with drugs that increase gastric pH: antacids, H2 antagonists and proton pump inhibitors, as these drugs can reduce absorption of ulipristal acetate • Avoid use with liver enzyme-inducing drugs and within 28 days of stopping them. These include: *Carbamazepine* *Phenobarbital* *Phenytoin* *Rifampicin* *Ritonavir* *St John's Wort* *Modafinil* • Co administration of ulipristal acetate and P-glycoprotein substrates e.g. dabigatran etexilate and digoxin which should be taken at least $1^1/_2$ hours before or after ulipristal • Seek medical advice if taking ciclosporin • Avoid grapefruit juice • Avoid UPA if any progestogens have been taken in

	the 7 days prior to requesting EHC **If in doubt contact Medicines Information for advice ext 5960**	
Adverse Reactions (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)	Refer to Summary of product characteristics and BNF for further information. Most Commonly Reported: • Abdominal pain/discomfort • Headache • Nausea • Dizziness • Dysmenorrhoea • Altered timing of next bleed (most will have a bleed within 7 days of the expected time) • Also breast tenderness, fatigue, back pain, vomiting and mood disorders • See Summary of Product Characteristics for full list of uncommon/rare adverse reactions	**Treatment of adverse reactions** • If necessary seek appropriate emergency advice and assistance • Document the adverse reaction in the patient's medical records. The GP should also be informed with client consent • Any serious adverse drug reactions should be reported to the MHRA by the yellow card scheme. Guidance on its use is available at the back of the BNF or can be accessed via *(www.yellowcard.mhra.gov.uk)*
Advice to Patients: Written and Oral advice	• Provide the FPA leaflet or refer to the web based emergency contraception patient information. Offer	

(This should include the provision of a patient information leaflet)	the manufacturer's patient information leaflet (PIL) • Discuss mode of action, efficacy, how to take and possible side effects • Advise that UPA is only effective for UPSI within 120 hours • Explain that the Cu-IUD is considered a more effective method of emergency contraception and refer to an appropriate healthcare provider after supply of UPA-EC, where appropriate and acceptable • Advise that oral EC may be less effective if the individual has a higher weight or BMI • Advise that oral EC is ineffective if given after ovulation • Advise on action to take if vomiting occurs within 3 hrs • Advise that available data suggest that UPA does not disrupt an existing pregnancy or increase the risk of fetal abnormality • Advice that emergency contraception with ulipristal only gives protection for the current risk • Discuss and offer ongoing contraception • Advise to wait at least 5 days after taking UPA before starting or continuing a hormonal method of contraception and to use a barrier method/abstain from sex until effective contraceptive cover has been achieved: ➢ 7 days for CHC (except Qlaira) and progestogen only implant (i.e 12 days in total) ➢ 2 days for POP (i.e 7 days in total) ➢ 9 days for Qlaira (i.e 14 days in total) • Advise to seek medical advice if lower abdominal pain occurs as for all pregnancies the possibility of an ectopic should be considered • Advise to return for a pregnancy test in 3 weeks if the next period is more than 7 days delayed or lighter/shorter than normal, and after quick starting a hormonal method of contraception. • If breastfeeding, advise the need to stop for seven (7) days after taking the medication and in order to

	stimulate lactation during this time, it is advised that women express and discard the breast milk.
Follow up action	• Advise to return for a pregnancy test in 3 weeks if the next period is more than 7 days delayed or lighter/shorter than normal, and after quick starting a hormonal method of contraception
Storage	Locked drugs cupboard or briefcase for outreach use – store below 25 °C
Records to be Kept	The following minimum details should be documented in full in the client's notes: • Assessment of client need in relation to the supply of ulipristal • Relevant past and present medical history including drug history • Any reason for exclusion • Any known allergies • Date and time • Completion of the emergency contraception checklist including consent to the method • On the prescription record document drug name and strength • Route of administration • Advice given • Follow up required • PGD used • Any supply made outside the product licence • Any other relevant information that was provided to the patient • Any communication with other health care professionals • Record of name of health professional supplying the medicine (may be electronic)
Audit Arrangements	As per current Trust PGD Policy

References	• Faculty of Sexual and Reproductive Healthcare. Emergency Contraception Guidance (2017). • British National Formulary www.bnf.org.uk • The Electronic Medicines compendium http://www.medicines.org.uk/emc/ • Policy and Procedure for the supply and/or administration of medicines under a patient group direction (2015). York Teaching Hospital. • The UK Medical Eligibility Criteria for Contraceptive Use (2016) • Faculty of Sexual and Reproductive Healthcare Quick Starting Contraception (2017) • Faculty of Sexual and Reproductive Healthcare (2017) Drug interactions with hormonal contraception • Faculty of Sexual and Reproductive Healthcare (2013) Use of Ulipristal Acetate (ellaOne®) in Breastfeeding Women. Update from the Clinical Effectiveness Unit (CEU)
Competency Requirements (attach any competency frameworks / documents)	The Nurse must be authorised by name under the current version of this PGD before working to it <u>Education, training, qualifications and competencies</u>: • Sexual health nurse • Clinical competence in sexual history taking. • Completion of the Trust PGD awareness session or Trust HUB e-learning. • Knowledge of the 3 available methods of emergency contraception as in the FSRH Guidance (2017) • Indications for emergency contraception and use of the FSRH algorithm to inform choice • Knowledge base of the contraindications to and restrictions for issuing UPA as well as interactions of UPA with other drugs • Competence in the above will be demonstrated by the undertaking of a local clinical competency

	based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health. • Assessment will be undertaken by the Lead Nurse/ANS or designated PGD assessor, who will be practising as an independent prescriber. • Maintain professional accountability with the NMC and ensure continual professional development • Receive clinical supervision and/or audit of case notes on an ongoing basis • Evidence of relevant continuing professional development identified through clinical supervision and appraisal • Regular attendance and participation in educational clinical governance sessions and nurse updates • Ensure keeps up to date with any changes to FSRH guidance relevant to this PGD

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION of Ulipristal acetate 30mg emergency contraception			
PGD Development / Review Team – responsible for PGD content			
Title	**Name**	**Signature**	**Date**
Lead Author	WENDY BILLSBOROUGH	Wendy Billsborough	15/1/2018.
Clinical Director Lead Approval	Dr IAN FAIRLEY		16/1/18.
Directorate Pharmacy Lead Approval	JILL McENANEY	Jill McEnaney	2.3.18
PGD Approved by the NMP/PGD Group			
Title	**Name**	**Signature**	**Date**
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		5.3.18
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes	p.p.	5/3/18

Authorisation to work within the PGD

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

Notes to the NMP/PGD Authorising staff

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

Staff authorised to work under this PGD	
Ward / Department	Sexual Health and Sexual Health Outreach Clinics
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed training programme

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date
This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved

When the review date is exceeded, this PGD ceases to be a legal document	
TEMPLATE DOCUMENTATION CONTROL	
The template documentation control refers to the PGD template not the completed PGD. **Do not alter this section.**	
Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	October 2015
Version:	1
Approved by	NMP/PGD Group
Review date:	October 2017