CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR
EMERGENCY CONTRACEPTION(Ulipristal Acetate 30mg)
VERSION: UPA 2018.2

Protocol Details	
Date comes into effect	1st October 2018
Date of expiry + review	30th September 2021 or in the light of significant changes in best practice
Staff characteristics	~~A~~ccredited community pharmacists supplying as part of the EHC scheme commissioned by Cumbria County Council Public Health Department who must: - Understand and accept the principles relating to patient group directions and relevant clinical situations and have undertaken training regarding working under PGDs. - Complete appropriate training in EHC supply, be up to date with and competent to work under the Faculty of Sexual and Reproductive Health Care Emergency Contraception Guidance. - Have made a CPPE Declaration of Competence **>> YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT <<**

Clinical Details	
Indication	Women who have requested emergency contraception for prevention of pregnancy
Inclusion criteria	**Competent woman (assess formally if aged under 16 or if competence in doubt) presenting within 120 hours of unprotected sexual intercourse, whether due to**: • No contraception used or failed barrier method of contraception. • Missed or incorrectly used combined or progestogen only contraceptive pill/ patch/ring. • Contraceptive pill vomited or method affected by diarrhoea or medicines. • Late contraceptive injection. • Expired or impalpable contraceptive implant. • Removal of IUC and failure of immediate replacement or partial/complete expulsion and the patient has had UPSI in the previous 5 days • Vomited supplied course of EC and represented within 3 hours of taking it.if the UPSI is within 120 hours • Loss of protection following commencement or change in contraceptive method. • Women who cannot be reassured that they are not at risk of pregnancy. Assessment of competency is satisfactory according to current guidelines eg Fraser guidelines and Mental Capacity Act All sexually active under 13 year olds must be discussed with the nominated child protection lead in the organisation and there should be a presumption that the case will be referred to children's social care.
Exclusion criteria	• If unwilling to cease hormonal contraception for 5 days after Ulipristal Acetate EC Levonorgestrel EC can be considered following full discussion surrounding efficacy of both methods of EC • If the women has taken LNG-EC in the previous 7 days – she can repeat LNG-EC, but due to the possibility of reduced efficacy UPA-EC should not be offered. • Breast feeding and **unwilling to stop breast feeding for 7 days**. • Hypersensitivity / previous severe adverse reaction to the active substance or any of its excipients. • Cannot exclude pregnancy if other episode of unprotected sexual intercourse in this cycle for which UPA has not been taken or in last three weeks if amenorrhoea / irregular periods or if last period more than 4 weeks ago if normally regular) • Severe asthma insufficiently controlled by oral glucuocortoids • Severe hepatic impairment.

	• Currently or have taken in the last 4 weeks any liver enzyme inducing drugs such as : carbamazepine, ciclosporin, griseofulvin, nevirapine, oxcarbazine, phenytoin,primidone and other barbiturates, rifabutin, rifampicin, ritonavir, St John's Wort, topiramate, ketoconazole, itraconazole, clarithromycin, telithromycin, nefadozone (this list is not exhaustive please check BNF) • Currently taking medicinal products that increase gastric pH (e.g proton pump inhibitors(e.g. omeprazole, lansoprazole, esomeprazole), antacids (ie mucogel) or H-2 antagonists (e.g.cimetidine,ranitidine) • Women with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose –galactose malabsorption • Women taking digoxin,verapamil or dabigatran • Acute porphyria
Special Precautions	• If the woman has used any hormonal contraception containing a progestogen in the 7 days prior to consultation they should be advised that there is a theoretical possibility that the efficacy of Ulipristal is reduced. Cu IUD is the preferred option, but LNG-EC may be offered as an interim measure.
Management of excluded patients	• Refer for emergency IUD. A copper IUD can be fitted up to 5 days after a single episode of UPSI in a cycle or up to 5 days after the earliest ovulation date expected within a regular cycle • If more than 120 hours, since episode of unprotected intercourse, refer to the next Sexual health Clinic or other suitable facility for assessment. • Pregnancy greater than 21 days can be excluded with a negative test, ideally using first morning urine. Note that this will not necessarily show positive for earlier pregnancies Refer other excluded women for urgent medical or Contraceptive review Offer levonorgestrel EC if appropriate
Action for patients not wishing to receive care under this PGD	Make women aware of alternative sources of treatment. (GP, Contraceptive Clinics or Young Person Clinics) Document refusal.

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR
EMERGENCY CONTRACEPTION(Ulipristal Acetate 30mg)
VERSION: UPA 2018.1

Description of Treatment	
Name of medicine	Ulipristal acetate 30mg tablet
Formulation and route	Oral tablet
Strength	30mg tablet
Dosage	1 tablet (30mg) to be taken within 120 hours after unprotected sexual intercourse . **Dose is to be taken at the consultation, supplies are not to be given to take away**
Repeated dose instructions	In the case of vomited tablets, where a woman returns having vomited the first dose within 3 hours of taking it, a replacement dose should be given (and taken)as soon as possible. UPA –EC may be used again if a women has already received UPA-EC earlier the cycle. Repeated administration of UPA-EC is well tolerated and can continue to delay ovulation for some time. However ovulation does eventually occur after UPA-EC in the majority if women. The available evidence demonstrates no risk of disruption of an existing implanted pregnancy or of fetal abnormality if UPA-EC is taken in early pregnancy.
Duration of treatment	Single course
Quantity to supply	**Dose is to be taken at the consultation, supplies are not to be given to take away**
Legal status	Pharmacy (P)
Special Precautions	Breastfeeding **–** UPA EC can be used during breastfeeding although the risk is unknown. Manufacturer recommends that the breastfeeding mother takes UPA EC immediately after feeding and expels and discards milk for 1 week following UPA
Adverse effects	Common side-effects (more than1/100 and less than1/10): mood disorders, headache, dizziness, nausea, vomiting, abdominal and/or pelvic pain, myalgia, back pain, dysmenorrhoea, breast tenderness, fatigue. Refer to BNF and SPC for complete list. If noted complete and submit the yellow card at the rear of the BNF or www.yellowcard.gov.uk for reporting any adverse reactions Doctor, nurse or patient can complete the yellow card.
Advice necessary	• Refer to Womens assessment forms (either paper or IT records) while the woman is present • Advise that EC is not 100% effective – pregnancy can still occur • Advise if less than 21 days post partum advise that risk of pregnancy is negligible • Advise that menstrual cycle timing may be disrupted. Disruption is more likelyif more than one course is taken in a menstrual cycle. • Give advice regarding action to take if tablets are vomited within 3 hours • Advise woman to seek medical advice if there is any lower abdominal pain, as ectopic pregnancies may occur following use, particularly at risk are women with a history of ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease. Women who become pregnant after EC use should seek medical follow up to exclude this. • Discuss sexually transmitted infections, especially chlamydia, and refer to GUM where appropriate • If under 25 to be offered chlamydia screening as part of the national screening programme • Following Ulipristal Acetate administration, defer hormonal method for following 5 days, then recommence method and advise barrier method or abstinence for following 7 days for combined hormonal methods, desogestrel POP and Implants and 2 days for traditional POP (outside of product licence) • Give woman a supply of condoms in addition to EC and stress need to consistently use a reliable method of barrier contraception, or abstain from intercourse, until the next period or until contraceptive method becomes effective

	• FPA leaflet to be emailed or link texted to patient) http://www.fpa.org.uk/sites/default/files/emergency-contraception-your-guide.pdf • Give the woman the information leaflet (PIL) from the medication packet • Referral to appropriate provider for ongoing contraception if not available at time of EC

Records and Follow Up	
Referral arrangements	As per local protocols.
Records to be kept	As per service documentation requirements, ensure: • Full history recorded • Fraser assessments to be completed for all women under 16 and a safeguarding assessment for all under 18 year olds (in line with local policies) or where competence is in doubt • Items or leaflets supplied to the woman •Document any adverse reaction •Comprehensive record made in sexual health notes / medical records
Follow up	Ensure woman is advised to return if any problems occur and if vomiting occurs within 3 hours of taking the tablet. Advise Women to attend an appropriate service with an Early Morning Urine (EMU) sample for a pregnancy test if no normal bleed within the next four weeks or if the next bleed is unusual in any way (light or heavy, painful etc)

Protocol, organisation and individual authorisation signatures can be found on the managerial content sheet along with other non-clinical details relating to this patient group direction.

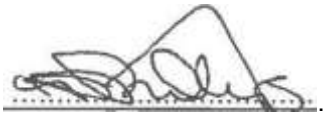
CUMBRIA COUNTY COUNCIL COMMISSIONED SERVICES

Managerial Content of Patient Group Direction for the Supply of emergency contraception (Ulipristal Acetate 30mg)

VERSION: UPA 2018.1

Protocol Owner	
Details of protocol owner	Name: Matt Phillips Position: Clinical Director, Sexual Health, Cumbria Partnership Foundation NHS Trust Voreda House, Portland Place, Penrith, Cumbria CA11 7BF

Protocol Details	
Date comes into effect	1st October, 2018
Date of expiry + review	30th September, 2021 or in the light of significant changes in best practice
Staff characteristics	**>>YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT<<**

Protocol Authorisation	
Lead Doctor	Name: Matt Phillips Position: Clinical Director Sexual Health, Cumbria Partnership Foundation NHS Trust Signature:  ……Date: ……28/09/18……..
Lead Pharmacist	Name: Jeffrey Forster Position: Pharmacist, Community Pharmacy Cumbria. Signature: …  ……...Date:29/09/18
Organisational Authorisation by Cumbria County Council	Name: Colin Cox Position: Director of Public Health, Cumbria County Council Signature: …  ……Date: …27/09/18……

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR

EMERGENCY CONTRACEPTION(Ulipristal Acetate 30mg)

VERSION: UPA 2018.1

Individual Authorisation

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT.

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

NOTE TO AUTHORISING MANAGERS: AUTHORISED STAFF SHOULD BE PROVIDED WITH AN INDIVIDUAL COPY OF THE CLINICAL CONTENT OF THE PGD AND A PHOTOCOPY OF THE AUTHORISATION SHEET SHOWING THEIR AUTHORISATION

Name of Professional	Signature	Authorising Manager	Date