Providing NHS Services

MANCHESTER CITY COUNCIL

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of ulipristal acetate 30mg tablet

By registered pharmacists for

Emergency Hormonal Contraception

In Community Pharmacy

Documentation details

Reference no:	
Version no:	1.0 (draft)
Valid from:	May 2020
Review date:	January 2022
Expiry date:	April 2023

Change history

	Not applicable	

Glossary

Abbreviation	Definition
CPPE	Centre for Pharmacy Postgraduate Education
UPSI	Unprotected sexual intercourse
EC	Emergency contraception
Cu-IUD	Copper intrauterine device
UKMEC	UK Medical Eligibility Criteria
SPC	Summary of product characteristics
FSRH	Faculty of Sexual & Reproductive Healthcare
UPA-EC	Ulipristal acetate emergency contraception
LNG-EC	Levonorgestrel – emergency contraception

1. PGD Working Group Membership

Name	Designation
Dr Connie Chen	GP, Chorlton Medical Centre, Manchester
Luvjit Kandula	Director of Pharmacy Transformation GMLPC
Richard Scarbourgh	Public Health Commissioning Manager - Sexual Health, Manchester City Council
Susan McKernan	Lead Pharmacist Manchester Health and Care Commissioning

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Manchester City Council authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Sexual health services provided by community pharmacies commissioned by Manchester City Council
Limitations to authorisation
The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of the their self-declaration and sign up to the current PGD

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Public Health, Manchester City Council	David Regan	David Regan	22/06/20
Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Doctor	Connie Chen	C.Chen	22/06/2020
Senior Pharmacist (Lead Pharmacist Manchester Health and Care Commissioning)	Susan McKernan	Susan McKernan	17/6/2020
Pharmacist Representative (Director of Pharmacy Transformation GMLPC)	Luvjit Kandula	Luvjit Kandula	22.6.2020

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets/templates may be used where appropriate in accordance with local policy.

3. Characteristics of staff

Qualifications and professional registration	▪ Pharmacist with current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within Manchester City Council area ▪ Pharmacist is required to have suitable indemnity insurance.
Initial training	▪ Has undertaken training in the use of PGDs ▪ Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply the treatment according to this PGD as detailed in the service specification. ▪ Has satisfied the competencies and completed the self-declaration form appropriate to this PGD, as detailed in the CPPE and NHS Health Education England *Declaration of Competence for pharmacy services – Emergency Contraception with the use of a Patient Group Direction* document (https://www.cppe.ac.uk/gateway/ehc) ▪ Is competent in the assessment of the individuals using Fraser guidelines
Competency assessment	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education England Declaration of Competence for pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction document.
Ongoing training and competency	▪ The pharmacist should be aware of any change to the recommendations for the medicine listed. ▪ Must be able to show regular update in the field of family planning and reproductive health care including emergency contraception. ▪ Must assess and maintain their own competence every three years on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for pharmacy services – Emergency Contraception with the use of a Patient Group Direction* document. ▪ It is the responsibility of the pharmacist to keep up-to-date with continuing professional development ▪ It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	A patient requesting oral emergency contraception who presents within 120 hours (5 days) of unprotected sexual intercourse (UPSI) or potential contraception failure
Criteria for inclusion Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI	Women with spontaneous menstrual cycles presenting within 120 hours (5 days) of UPSI or potential contraception failure (e.g. condom failure, severe vomiting/diarrhoea whilst on oral hormonal contraception), and who: • Have been given information regarding the other methods available for EC (see Advice to be given to the patient or carer) and provided with information on services that can provide them, but decides not to access them. (If a woman is referred on for a copper intrauterine device (Cu-IUD), ulipristal acetate EC should be given at the time of referral in case the Cu-IUD cannot be inserted or the woman changes her mind.) • Understand the risks, benefits and side effects of treatment with ulipristal acetate. • Meet Fraser guidelines, if under 16 years of age. ***Note children under 13 years of age must be notified to the local Safeguarding Team; however, this should not prevent treatment if considered necessary under this PGD.*** • Are competent to consent to treatment. • Has reached the menarche • Must attend in person for supply of medication to be Given NB. For the duration of the COVID-19 pandemic, to reduce risk of transmission, pharmacists may use their professional judgement on how they provide emergency hormonal contraception. For example by telephone consultation. This is provided they take steps to minimise patient risk and are mindful of potential for abuse with due regard to safeguarding. Any provision and use of professional judgement must give due consideration to the latest advice given by the General Pharmaceutical Council and Royal Pharmaceutical Society. Supplies made utilising this temporary adjustment should be recorded as such.
Criteria for exclusion	• UPSI more than 120 hours (5 days) ago • Use of hormonal contraception, levonorgestrel or any progestogen within the previous 7 days • Liver enzyme inducing medications currently or within the previous 28 days • Drugs that raise gastric pH (including proton pump inhibitors, antacids and H2-receptor antagonists • Allergy / known product ingredients

	• Severe asthma treated with oral glucocorticoid. • Known pregnancy. (Suspected pregnancy should be excluded using a pregnancy test[1].) • Unexplained or unusual vaginal bleeding. • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. • If the patient is receiving any concomitant medication or treatment, it is the responsibility of the pharmacist to ensure that treatment with the medicines detailed in this PGD is appropriate • Where necessary this should be sought from an appropriate healthcare professional (e.g. patient's GP, sexual health clinic doctor) and this must be recorded as having been sought before the medicine is given
Cautions including any relevant action to be taken	• If breast feeding advised to avoid or express and discard for 7 days after ulpristal acetate • Refer to the current version of the UK Medical Eligibility Criteria for Contraceptive use (UKMEC; https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016/) and where necessary explain the benefits and risks.
Action to be taken if the patient is excluded	• If commissioned Consider suitability of Levonorgestrel via PGD • Refer to a doctor or to the nearest available contraceptive clinic as appropriate. • Document action taken
Action to be taken if the patient or carer declines treatment	▪ Inform patient/carer re risks of not receiving treatment compared to the benefits. ▪ Refer to a doctor or to the nearest available contraceptive clinic as appropriate. ▪ Document action taken.
Arrangements for referral for medical advice	***Refer to the appropriate medical practitioner in the care pathway***

5. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30 mg tablet
Legal category	POM
Route / method of administration	Oral
Indicate any off-label use (if relevant)	Not applicable Check product SPC to identify off label usage as this can vary between manufacturers.

[1] Although there is potential for a false negative where fertilisation occurred less than 3 weeks previously, the FSRH CEU recommends that ulipristal acetate can be used more than once in the same cycle or can be used for a recent episode of UPSI even if there has been an earlier episode of UPSI outside the treatment window (>120 hours) (outside product licence), as there is no evidence to indicate ulipristal acetate increases the risk of miscarriage or developmental abnormality Please note in this PGD use is only allowed within the treatment window of ≤120 hours (5 days).

Dose and frequency of administration	• One tablet to be taken as a single dose as soon as possible and no later than 120 hours (5 days) after UPSI. • If vomiting occurs within three hours of taking, another dose should be taken immediately, but this must fall within the 120 hours (5 days) since UPSI occurred.
Duration of treatment	Single episode of treatment which may be repeated in the same cycle if appropriate.
Quantity to be supplied	Single dose of ulipristal acetate 30 mg. Patients should be observed taking the medication unless they are breast feeding, when they can be allowed to take away for later consumption if necessary, but this must occur within the 120 hour (5 day) window and breast milk should be expressed and discarded for 7 days after taking ulipristal acetate. Nb. For the duration of the COVID-19 pandemic, the patient does not need to be observed taking the medication. The pharmacist should seek assurance from the patient they will take the dose as soon as possible and within 120 hours (5 days) of UPSI or potential contraception failure when taking away.
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	▪ UPA interferes with progestogen containing medication ▪ If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction see Appendix 1 of BNF (https://www.medicinescomplete.com/mc/) or the Summary of Product Characteristics (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF) or refer to *Clinical Guidance: Drug Interactions with Hormonal Contraception* (FSRH, January 2019) or www.hiv-druginteractions.co.uk ▪ In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given.
Identification & management of adverse reactions	**Side Effects**

Common	**Uncommon**
	Influenza
	Appetite disorders
Mood disorders	Emotional disorder Anxiety Insomnia Hyperactivity disorder Libido changes
Headache	Somnolence

Dizziness	Migraine
	Visual disturbance
Nausea* Abdominal pain* Abdominal discomfort Vomiting*	Diarrhoea Dry mouth Dyspepsia Flatulence
	Acne Skin lesion Pruritus
Myalgia Back pain	
Dysmenorrhea Pelvic pain Breast tenderness	Menorrhagia Vaginal discharge Menstrual disorder Metrorrhagia Vaginitis Hot flush Premenstrual syndrome
Fatigue	Chills Malaise Pyrexia

*Symptom which could also be related to an undiagnosed pregnancy (or related complications)

* Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time.
** If the next menstrual period is more than 5 days overdue, pregnancy should be excluded. If pregnancy occurs after treatment with ulipristal acetate, the possibility of an ectopic pregnancy should be considered. Severe abdominal pain may be an indication of ectopic pregnancy.

For a full adverse effects profile, refer to the Summary of Product Characteristics (SPC – www.medicines.org.uk) or the most current edition of the British National Formulary (BNF – www.bnf.org)

Management of and reporting procedure for adverse reactions

In the event of any adverse reaction:

- Record the adverse reaction in the patient consultation note
- Inform the patient's GP if the patient consents to this

If appropriate report the adverse reaction under the Yellow Card scheme

(forms can be found at the back of the BNF or completed online; http://yellowcard.mhra.gov.uk)

Written information to be given to patient or carer

The patient/carer should be given or directed to the following written information if appropriate:

- The product specific patient information sheet supplied with the medicine.
- A copy of the Family Planning Association (FPA) leaflet 'Your guide to emergency contraception' (http://www.fpa.org.uk/resources/downloads)

Patient advice / follow up

The patient/carer should be given the following information verbally if

treatment	appropriate and requested: ▪ Advise women that the Cu-IUD is the most effective method of EC. ▪ Advise women that UPA-EC has been demonstrated to be more effective than LNG-EC. ▪ EC providers should advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. ▪ Effectiveness of method is dependent on length of time from UPSI / potential contraceptive failure to treatment. ▪ Beneficial effects, side effect and risks should be discussed. ▪ Advise women that after oral EC there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle. ▪ How to take the pill correctly, preferably as an immediate dose in the pharmacy. ▪ Breast feeding mothers may be allowed to take away with them to allow them to feed their child before taking. This should only occur if it fits within the allowed time limits. They express and discard for 7 days after taking ulpristal acetate ▪ If vomiting occurs within three hours of taking, a repeat dose is required, but must be given within the 120 hours (5 days) since UPSI. ▪ When to seek further medical advice ▪ To refer to Sexual Health Clinic or GP if no / light period up to three weeks after treatment. ▪ Advise women that oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or abstain from sex to avoid further risk of pregnancy. ▪ Discuss on going contraception ▪ Discuss long-acting reversible contraception and give written information that is in line with NICE guidance, CG 30, updated July 2019. ▪ Encourage use of condoms and reinforce the safer sex message. ▪ Recommend sexually transmitted infections screening. ▪ Supply or recommend condoms as detailed in the service specification. ▪ Use of the product outside the terms of its licence should be discussed with the patient, including the reasons why this may be necessary. ▪ Advise where the patient will continue to use a hormonal method of contraception it should not be re-started within 5 days of taking UPA ▪ Advise that no medication containing progesterone should be started within 5 days
Records	PharmOutcomes should be used to record all consultations as required by the service specification. Supplies made utilising this temporary adjustment for COVID-19 should be recorded as such.

	Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or if the patient was 17 at the conclusion of the treatment, until their 26th birthday. (Records Management Code of Practice for Health and Social Care 2016; https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016

6. Key references

Key references	1. BNF – ulipristal-acetate 30mg https://bnf.nice.org.uk/medicinal-forms/ulipristal-acetate.html 2. BNFc - ulipristal-acetate 30mg https://bnfc.nice.org.uk/drug/ulipristal-acetate.html 3. Summary of Product Characteristics EllaOne ® ulipristal-acetate 30 mg tablets https://www.medicines.org.uk/emc/product/6657/smpc 4. Faculty of Sexual & Reproductive Healthcare – Emergency Contraception (December 2017) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ 5. Faculty of Sexual & Reproductive Healthcare – UK Medical Eligibility Criteria (September 2019) https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016/ 6. Faculty of Sexual & Reproductive Healthcare – Drug Interactions with Hormonal Contraception (January 2019) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ 7. NICE CKS – Contraception – emergency (September 2019) https://cks.nice.org.uk/contraception-emergency 8. NHS Digital – Records Management Code of Practice for Health and Social Care (July 2016) https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016 9. CPPE – Declaration of Competence Factsheet (May 2017) https://www.cppe.ac.uk/services/declaration-of-competence

7. Registered health professional authorisation sheet

Supply of ulipristal acetate 30 mg for Emergency Hormonal Contraception
Version. 1.0 **Valid from:** May 2020 **Expiry: April** 2023

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of INSERT NAME OF ORGANISATION for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.