This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Ulipristal Acetate 30mg tablet

By registered health care professionals for

Emergency contraception

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 150

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021
2	Minor word changes to ensure clarity to the PGD	September 2023

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Deputy to Chief Pharmacist/ Pharmaceutical Adviser			
Deputy to Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A

5. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises • Specific training in sexual health and/or emergency contraception, or equivalent experience
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs • Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or advised in the RCN training directory • The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

6. Clinical Conditions

Clinical condition or situation to which this PGD applies	• To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or • regular contraception has been compromised or used incorrectly
Inclusion criteria	• Any individual presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly • No contraindications to the medication • Informed consent given

Exclusion criteria	• Informed consent not given • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines • Individuals 16 years of age and over and assessed as lacking capacity to consent • This episode of UPSI occurred more than 120 hours ago. **NB**: 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 • Known or suspected 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) • Less than 21 days after childbirth • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD) • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • Use of levonorgestrel or any other progestogen in the previous 7 days (ie, hormonal contraception, hormone replacement therapy or use for other gynaecological indications) • Concurrent use of antacids, proton-pump inhibitors or H_2-receptor antagonists • Severe asthma controlled by oral glucocorticoids • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping
Cautions (including any relevant action to be taken) *(continued)*	• 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 • If individual vomits within three hours from ingestion, a repeat dose may be given • Body Mass Index (BMI) >26kg/m2 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

Cautions (including any relevant action to be taken) *(continued)*	• Breast feeding – advise to express and discard breast milk for 7 days after ulipristal dose • The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section 'Written information and further advice to be given to individual' • 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 A detailed list of cautions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options

7. Details of the medicine

Name, form and strength of medicine	Ulipristal acetate 30mg tablet
Legal category	Pharmacy (P)
Indicate any off-label use (if relevant)	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). This PGD includes off-label use in the following conditions: • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption • Severe hepatic impairment Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Route/method of administration	Oral
Dose and frequency	One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI
Quantity to be administered and/or supplied	Appropriately labelled pack of one tablet

Maximum or minimum treatment period	• A single dose is permitted under this PGD
	• If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD
	• Repeated doses can be given within the same cycle. **NB**:
	  ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)
	  ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)

Storage	Room temperature

Adverse effects	The following side effects are common with Ulipristal acetate (but may not reflect all reported side effects): • Abdominal pain or discomfort • Breast tenderness • Dizziness • Dysmenorrhea • Fatigue • Headache • Mood changes • Muscle pain (myalgia) • Nausea or vomiting • Pelvic pain • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

8. Patient information

Verbal/Written information to be given to patient or carer *(continued)*	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request • All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception • Ensure that a patient information leaflet (PIL) is provided within the original pack • If vomiting occurs within three hours of taking the dose, the individual should return for another dose • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception • Provide advice on ongoing contraceptive methods, including how these can be accessed • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following Ulipristal Acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain

Verbal/Written information to be given to patient or carer *(continued)*	from intercourse) should be advised until fully effective • 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 • Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
Follow-up advice to be given to patient or carer	• The individual should be advised to seek medical advice in the event of an adverse reaction • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned • Pregnancy test as required (see advice to individual above) • Individuals advised how to access on-going contraception and STI screening as required

9. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. Electronic medicines compendium available online: https://www.medicines.org.uk
6. NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
7. Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - fsrh-guideline-emergency-contraception03dec2020-amendedjuly2023-11jul%20(1).pdf
8. 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-with-hormonal-contraception-5may2022.pdf
9. 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
10. FSRH CEU Guidance: Drug Interactions Between HIV Antiretroviral Therapy (ART) and Contraception (February 2023): hiv-drug-interactions-with-contraception-07feb2023.pdf

10. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

11. Appendix C

Records
The consent of the individual and: • If individual is under 13 years of age record action taken • If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken • If individual over 16 years of age and not competent, record action taken • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical history, including medication history. Examination finding where relevant eg, weight • Any known drug allergies • Name of registered health professional operating under the PGD • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Any supply outside the terms of the product marketing authorisation • Recorded that supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.