Salford
Integrated Care Partnership

PATIENT GROUP DIRECTION (PGD)

SUPPLY OF ULIPRISTAL 30MG TABLET

By registered pharmacists for

Emergency Hormonal Contraception

In Community Pharmacy

Documentation details

Version no:	2.4
Valid from:	1st July 2023
Review date:	30th June 2024
Expiry date:	30th June 2025

Change history

Version	Summary of Changes	Action by	Date
1.0		Alicia Robson	March 2017
2.0	• Updated in line with new FSRH guidance published March 2017 • New recommendations - all products containing progestogen or progesterone are avoided for 5 days after ulipristal has been taken to avoid compromising the ability of ulipristal to delay ovulation.	Alicia Robson	December 2017
2.1	None	Alicia Robson	October 2019
2.2	• Moved PGD to national template • Added in temporary supply adjustment measures in view of COVID-19 pandemic. Sections updated include: - Quantity to be supplied - Patient advice/follow up treatment - Records	Tsz Shan Mak	June 2020
2.3	• Removed link to FPA Emergency Contraception leaflet download as document currently not available. • Extra review date included (August 2022 – to review and potentially remove the option for remote consultations which were required during COVID-19 pandemic.	Alicia Robson	June 2022
2.4	• Updated to reflect CCG changes to ICB - Logo changed	Tsz Shan Mak	May 2023

	- CCG reference changed to NHS GM Salford locality • Updated link for online BNF • Link added for NICE CG30 • Temporary supply adjustment measures in view of COVID-19 pandemic changed to wording to support any future government directed infection prevention and control protocols. Sections updated include: - Quantity to be supplied - Patient advice/follow up treatment - Records		

Glossary

Abbreviation	Definition
CPPE	Centre for Pharmacy Postgraduate Education
UPSI	Unprotected sexual intercourse
IUD	Intrauterine device
SPC	Summary of Product Characteristics
FSRH	Faculty of Sexual & Reproductive Healthcare

1. PGD template development

Developed/Reviewed by:	
Name	**Designation**
Dr Peter Budden	GP Prescribing Lead, NHS GM Salford locality
Claire Vaughan	Head of Medicines Optimisation, NHS GM Salford locality
Alicia Robson	Medicines Optimisation Pharmacist, NHS GM Salford locality
Tsz Shan Mak	Medicines Optimisation Pharmacist, NHS GM Salford locality

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.

Salford 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 Salford 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 training received.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**

Deputy Director of Public Health, Salford City Council	Gillian McLauchlan		3rd July 2023
Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Doctor **(GP Prescribing Lead, NHS GM Salford locality)**	Dr Peter Budden	Signatories have approved this PGD using approved electronic authorisation systems (Email trail kept on locality computer network)	16/06/2023
Senior Pharmacist **(Associate Director Clinical & Care Professional Leadership and Head of Medicines Optimisation Salford, NHS GM Salford locality)**	Claire Vaughan	Signatories have approved this PGD using approved electronic authorisation systems (Email trail kept on locality computer network)	16/06/2023

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 Salford City Council area
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 appropriate to this PGD, as detailed in the Centre for Postgraduate Pharmacy Education (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/services/docs/emergency%20contraception.pdf). • 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 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 between 72 – 120 hours 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 between 72 – 120 hours of UPSI or potential contraception failure (e.g. condom failure, severe vomiting/diarrhoea whilst on oral hormonal contraception), and who: • Have no known contraindications to progestogen in their known medical history. • Understand the risks, benefits and side effects. • 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. • Have been offered the option of an intrauterine device (IUD). If referring for a post-coital intrauterine device, oral emergency hormonal contraception should be supplied if within PGD and acceptable to the patient. • Has reached the menarche Patient has received ulipristal acetate emergency contraception but has vomited within **three** hours of taking it (provided they are still within 120 hours of UPSI).
Criteria for exclusion	• UPSI up to 72 hours ago – Advise woman that levonorgestrel is available - refer to levonorgestrel PGD. • UPSI more than 120 hours ago. • Allergy/known intolerance to progestogen or other product ingredients. • Confirmed pregnancy. (Suspected pregnancy should be excluded using a pregnancy test.) • Women less than 21 days post-partum. • Women less than 5 days following termination of pregnancy or miscarriage, • Undiagnosed vaginal bleeding. • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. • Third party requests. • Current contraception method used correctly. • Acute porphyrias. • Severe asthma treated by oral glucocorticoids. • Currently taking (or stopped taking up to four weeks ago) hepatic enzyme inducing medication including: ○ Primidone, phenobarbital, phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, rifabutin, ritonavir (long term), griseofulvin, efavirenz and nevirapine.

	• *(See BNF and ellaOne SPC https://www.medicines.org.uk/emc/medicine/22280/SPC/ellaOne+30+mg/#PRODUCTINFO for full details)*
Cautions including any relevant action to be taken	• Effectiveness of ulipristal could be reduced if a progestogen has been taken prior to taking ulipristal. • All products containing progestogen or progesterone should be avoided for 5 days after ulipristal has been taken to avoid compromising the ability of ulipristal to delay ovulation. Barrier methods should be used until next menstrual period. • Severe intestinal malabsorption syndromes e.g. Crohn's disease, might impair the efficacy of ulipristal. Advise patient accordingly. • Efficacy and absorption of ulipristal may be reduced with concomitant use of proton pump inhibitors, H_2 receptor antagonists and other drugs that increase gastric pH. Advise patient accordingly. • Severe hepatic impairment. • Breast feeding is not recommended for 7 days after taking ulipristal. ***The Copper-IUD can offer a more effective option and it is important that patients understand the risk of emergency contraception failure.***
Action to be taken if the patient is excluded	• Refer to appropriate doctor or sexual health clinic. • Document all actions taken.
Action to be taken if the patient or carer declines treatment	• Make individual aware of the risks of not receiving treatment. • Refer to doctor or sexual health clinic. • Document all actions 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 (ellaOne®) 30mg tablet
Legal category	POM
Route / method of administration	Oral
Indicate any off-label use (if relevant)	Not applicable.
Dose and frequency of administration	One 30mg tablet to be taken as a single dose between 72 and 120 hours after UPSI. If patient experiences vomiting within three hours of taking ulipristal, a second supply is allowed providing it is taken within 120 hours of UPSI.
Duration of treatment	Single episode of treatment – treatment may be repeated in the same cycle if appropriate. See Dose and Frequency section.
Quantity to be supplied	Single dose of ulipristal acetate 30 mg supplied in a suitably labelled box. (Labelled in accordance with current legislation)

<table>
<tr><td></td><td>It is good practice to observe the patient consuming the medication unless they are breast feeding, when they can be allowed to take it away for later consumption if necessary. This must occur within the 120 hour window.

NB. In line with any future government directed infection prevention and control protocols, to reduce risk of transmission, pharmacists may use their professional judgement on how they provide emergency hormonal contraception.
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.

For example by telephone consultation and delivered to patient. Supply via this method meant that patient does not need to be observed taking the medication. The pharmacist should seek assurance from the patient that they will take the dose as soon as possible and within 120 hours of UPSI or potential contraception failure when taking away.

Supplies made utilising this temporary adjustment should be recorded as such.</td></tr>
<tr><td>Storage</td><td>Store below 25°C. Store in the original packaging to protect from moisture. Keep the blister in the outer carton to protect from light.</td></tr>
<tr><td>Drug interactions</td><td>• If the patient is taking any concomitant medication or treatment it is the pharmacist's responsibility to ensure that treatment with the drug detailed in this PGD is appropriate. (For drug interaction see Appendix 1 of BNF (https://bnf.nice.org.uk/interactions/) or the Summary of Product Characteristics (SPC) (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF)
• 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.
• If the requirements of this PGD cannot be complied with, the patient must be referred to a suitable independent prescriber.)</td></tr>
<tr><td>Identification & management of adverse reactions</td><td>
<table>
<tr><th colspan="2">Very common and common adverse effects</th></tr>
<tr><td>Abdominal pain</td><td>Back pain</td></tr>
<tr><td>Diarrhoea</td><td>Dizziness</td></tr>
<tr><td>Fatigue</td><td>Gastro-intestinal disturbances</td></tr>
<tr><td>Headache</td><td>Menstrual irregularities</td></tr>
<tr><td>Muscle spasms</td><td>Nausea</td></tr>
<tr><td>Vomiting</td><td></td></tr>
</table>
</td></tr>
</table>

	For a full adverse effects profile, refer to the SPC (www.medicines.org.uk) or the most current edition of the BNF (https://bnf.nice.org.uk/)
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 at http://yellowcard.mhra.gov.uk)
Written information to be given to patient or carer	The patient should be given the following written information if appropriate: • The product specific patient information sheet supplied with the medicine.
Patient advice / follow up treatment	The patient should be given the following information verbally if appropriate and requested: • Effectiveness of method, dependent on length of time from UPSI/ potential contraceptive failure to treatment. • Beneficial effects, side effects and risks should be discussed. • Effectiveness of Ulipristal could be reduced if a progestogen has been taken prior to taking Ulipristal. • The FSRH recommends that all products containing progestogen or progesterone should be avoided for **5 days** after ulipristal has been taken to avoid compromising the ability of Ulipristal to delay ovulation. Barrier methods should be used until next menstrual period. • 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. • Manufacturer advises that breast feeding should be avoided for 7 days after taking ulipristal. • If vomiting occurs within three hours of taking, a repeat dose is required. • When to seek medical advice. • To refer to Sexual Health Clinic or GP if no/ light period up to 3 weeks after treatment. • Discuss on-going contraception including Quick Starting Contraception guidance (recommending starting contraception >5 days after Ulipristal emergency contraception has been taken, with additional protection as appropriate for the method used). • Discuss long-acting reversible contraception and give written information that is in line with NICE guidance, CG30 October 2005 https://www.nice.org.uk/guidance/cg30 • Supply and/or encourage use of condoms and reinforce the safer sex message. *NB: If supplies made utilising temporary adjustment in line with government directed infection prevention and control protocols, condoms could be delivered to patient along with ulipristal.* • Recommend sexually transmitted infections screening.

Records	The pharmacist must keep a record of the consultation as required in the service specification for a period of time in line with records management: NHS code of practice (https://www.nhsx.nhs.uk/information-governance/guidance/records-management-code/) and service specification. The minimum required information to be collected is: • Informed consent has been given • Patient's name, postcode, date of birth. • Dose supplied. • Date administered/issued – if not, detail why. • Advice given. • Supply documented on Patient Medical Record. • Adverse drug reactions documented. • Name, signature and GPhC number of pharmacist who supplied the medication. • Expiry date • Batch number • If under 16 years 'Fraser Competence Checklist' completed *NB: Supplies made utilising temporary adjustment in line with government directed infection prevention and control protocols, it should be recorded as such.* Records management: NHS Code of Practice recommends the following storage periods for Sexual Health paper records: • **8 years (in adults) or until 25th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death**. Computerised patients medication records can be used where considered appropriate. Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

6.Key references

Key references	1. Faculty of Sexual and Reproductive Healthcare, Clinical Effectiveness Unit: • Emergency Contraception. Clinical Guidance, March 2017 (amended December 2020) Accessed on 11th May 2023. • Contraceptive Choices for Young People. Clinical Guidance. March 2010, amended May 2019. Accessed 11th May 2023. 2. Manufacturers' Summaries of Product Characteristics (SPC) • ellaOne® 30mg tablet HRA Pharma UK and Ireland Ltd. Date of last revision of the text 1st January 2021. Accessed 11th May 2023.

3. General Pharmaceutical Council
   - Standards for pharmacy professionals. May 2017. Accessed 11th May 2023.

4. Centre for Pharmacy Postgraduate Education
   - Declaration of competence for community pharmacy services; Emergency Contraception Service with the use of a Patient Group Direction. Accessed 11th May 2023.

7.Registered health professional authorisation sheet

Supply of ulipristal acetate 30 mg for Emergency Hormonal Contraception
Version. 2.4 **Valid from:** 1st July 2023 **Expiry:** 30th June 2025

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.