PATIENT GROUP DIRECTION (PGD)

Supply of levonorgestrel 1500 microgram tablet by registered pharmacists for second line emergency contraception in community pharmacy in Bury

Version 6.0

Valid from: 31/08/2023

Expires on: 30/08/2025

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.

This PGD has been produced by Strategic Pharmacy and Medicines Optimisation Team at GM Integrated Care.

DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Bury Council
Address:	3 Knowsley Place, Knowsley Street, Bury BL9 0SN
Telephone:	0161 253 5000

Revision History

The latest and master version of the unsigned PGD is held by Strategic Pharmacy and Medicines Optimisation Team at GM Integrated Care.

Revision Date and Actioned By	Summary of Changes		Version
30/06/2021 K Osowska	Final formatting		5.0
14/06/2023 K Osowska	Review of the PGD		5.1
	Section of the PGD	Changes made	
	Title of the PGD	Removed word “administration” from the title	
	Characteristics of staff. Suggested supporting learning	Removed section “Suggested supporting learning” as not needed because all required and recommended trainings are listed in sections on initial training and continued training. Statement: “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” was removed as this is duplication of the 4th bullet point listed in section on initial training and competency assessment.	
	Characteristics of staff. Initial training and competency assessment	Changed “PGD e-learning module” which is no longer available to “eLfH e-learning programme” which is recommended by the national PGD template for levonorgestrel EC (v2.0)	
		Added course on emergency hormonal contraception accredited by CPPE (as per the national PGD template for levonorgestrel EC, v2.0)	

		Added information that **level 2** safeguarding courses are required. This is in line with national PGD template for levonorgestrel EC, v2.0. Added hyperlinks to the required courses.	
	Characteristics of staff. Continued training and competency	Changed bullet point: "The pharmacist should be aware of any change to the recommendations for the medicine listed" to "Pharmacists operating under this PGD: Are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required" (it's in line with the national PGD template for levonorgestrel EC, v2.0)	
14/06/2023 K Osowska	Clinical condition or situation to which the direction applies. Criteria for inclusion.	There was clarification provided that Cu-IUD is the most effective method of EC within five days of UPSI or within five days from earliest estimated ovulation.	5.1
		Advice on supply of levonorgestrel EC during COVID-19 pandemic has been amended to generic advice in case of any pandemic.	
	Clinical condition or situation to which the direction applies. Cautions.	2 bullet points added in line with national PGD template for levonorgestrel EC, v2.0 "Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them - see dose frequency section. " "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. If levonorgestrel is to be given, see dosage section".	
14/06/2023	Clinical condition or situation to which the direction applies. Action to be taken if individual excluded or declines treatment.	Statement: "Refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options". amended to "Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if	5.1

		appropriate and/or provide them with information about further options." This is in line with national PGD template for levonorgestrel EC, v2.0	
14/06/2023 K Osowska	Description of treatment. Unlicensed /off label use	Added bullet point: "Individuals with previous ectopic pregnancy" As per levonorgestrel EC summary of product characteristics it is not recommended in women with medical history of ectopic pregnancy. However, FSRH Guideline on Emergency Contraception states that levonorgestrel EC can be used (off-label) in women with medical history of ectopic pregnancy. This is reflected within the national PGD template for levonorgestrel EC, v2.0. Also, NICE CKS on ectopic pregnancy states that "*...the rates of ectopic pregnancies in women using (…) the emergency hormonal contraception are similar to those in the general population".*	5.1
	Description of treatment. Quantity to be administered and /or supplied	Advice on administration of levonorgestrel EC during COVID-19 pandemic has been amended to generic advice in case of any pandemic.	
	Description of treatment. Drug interactions	Advice on and link to Medicine Information at Liverpool was removed as this is no longer available.	
	Review and update of references. Formatting.		
10/07/2023 K Osowska	Characteristics of staff.	Addition of statement: "The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies" in line with the national PGD template for levonorgestrel EC, v2.0	6.0
	Final formatting		

Approvals

This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF APPROVAL	VERSION
Dr Catherine Fines	Chair, GM ICS, NHS Bury	17.07.2023	6.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, Greater Manchester Integrated Care	10.07.2023	6.0
Jon Hobday	Director of Public Health, Bury Council	16.08.2023	6.0
Louise Gatley	Director of Services, GM LPC	31.07.2023	6.0

Distribution

This PGD has been distributed, during its review, to:

NAME	TITLE	DATE	VERSION
Dr Catherine Fines	Chair, GM ICS, NHS Bury	23.06.2023	5.1
		10.07.2023	6.0
Louise Gatley	Director of Services, GM LPC	21.06.2023	5.1
		10.07.2023	6.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, Greater Manchester Integrated Care	15.06.2023	5.1
		10.07.2023	6.0
Salina Callighan	Head of Medicines Optimisation, GM ICS, NHS Bury	23.06.2023	5.1
		10.07.2023	6.0
Shenna Paynter	Commissioning Manager, Bury Council	21.06.2023	5.1
		10.07.2023	6.0

PGD Development

Originally developed by:	Stephen Woods (author)	Senior Medicines Optimisation Pharmacist, Greater Manchester Joint Commissioning Team
	Dr Jeffrey Schryer	Chair, NHS Bury Clinical Commissioning Group
	Dipesh Raghwani	Clinical Lead, GM LPC
Reviewed by:	Karina Osowska (reviewer)	Advanced Medicines Optimisation Pharmacist Greater Manchester Integrated Care

Date applicable:	31st August 2023

Review date:	1st June 2025
Expiry date:	30th August 2025

PGD Authorisation

This Patient Group Direction has been approved for use in the Oldham Council area by:

Designation	Name	Signature	Date
Doctor (Chair, GM ICS, NHS Bury)	Dr Catherine Fines		17.07.2023
Senior Pharmacist (Strategic Medicines Optimisation Pharmacist Greater Manchester Integrated Care)	Andrew Martin		10.07.2023
Pharmacist Representative (Director of Services, GM LPC)	Louise Gatley		31.07.2023
Authorising Signatory (Director of Public Health, Bury Council)	Jon Hobday		16.08.2023

1. Characteristics of staff

Qualifications and professional registration	• Pharmacist with current General Pharmaceutical Council registration. • Pharmacist who works in a community pharmacy within Bury Council area.
Initial training and competency assessment	The registered pharmacist authorised to operate under this PGD must: • Have successfully completed 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. • Have successfully completed eLfH PGD e-learning programme. • Have successfully completed locally required relevant contraception and emergency contraception courses accredited by CPPE. • Have 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 Service with the use of a Patient Group Direction document.** (https://www.cppe.ac.uk/services/declaration-of-competence#navTop) • Be assessed as competent (see Appendix A). • Have successfully completed locally required training (including updates) in safeguarding children and vulnerable adults, level 2 accredited by CPPE. • Have successfully completed locally required training in sexual health accredited by CPPE. • Be competent in the assessment of the individuals using Fraser guidelines.
Continued training and competency	Pharmacists operating under this PGD: • Are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • 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 Service with the use of a Patient Group Direction document.** • Are responsible for keeping up-to-date with continuing professional development. • Are responsible for maintaining 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 organisational policies.

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 their self-declaration and sign up to the current PGD.

2. Clinical condition or situation to which the direction applies.

Clinical condition or situation to which this PGD applies	• Sexual health services provided by community pharmacies commissioned by Bury Council. A patient requesting emergency contraception (EC) who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential contraception failure and refuses or cannot be treated with first line EC ulipristal acetate 30mg. • There are two emergency contraception (EC) PGDs used within Bury Council. First line EC is ulipristal 30mg and second line EC is levonorgestrel 1500micrograms.
Criteria for inclusion	Woman with spontaneous menstrual cycles presenting within 72 hours of UPSI or potential contraception failure (e.g. condom failure, severe vomiting/diarrhoea whilst on oral hormonal contraception), and who: • Gives informed consent. • Refuses or cannot be treated with first line EC ulipristal 30mg. • Has been provided with information that insertion of 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 however decides not to access this service (see section 'Advice to be given to the patient or carer'). • Has been provided with information regarding Cu-IUD and it is appropriate and acceptable. This patient can be given levonorgestrel EC at the time of referral to appropriate health service, in case the Cu-IUD cannot be inserted or the woman changes her mind. • Has no known contraindications to progestogen in the known medical history and any excipients listed in the product SPC. • Understands the risks, benefits and side effects of treatment with levonorgestrel. • Meets Fraser guidelines, if under 16 years of age. **Note** children under 13 years of age must be notified to the local Safeguarding Team and the pharmacist should follow the local safeguarding policy, however, this should not prevent treatment if considered necessary under this PGD. • Is 16 years of age and over and assessed as having capacity to consent to treatment. • Has reached the menarche. • Vomited within three hours of taking levonorgestrel EC; repeat dose can be provided, but this must fall within the 72 hours since UPSI occurred. • Must attend in person for supply of medication to be given. **NB. In the event of pandemic pharmacists may use their professional judgement on how they provide emergency hormonal contraception e.g. via remote telephone consultation. This is provided they take**

	steps to minimise patient risk and be 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 **(Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it may be outside the remit of the PGD and another form of authorisation may be suitable.)**	• Patient who decides to access first line EC treatment with ulipristal acetate 30mg. • Use of ulipristal acetate emergency contraception within the last 5 days. • UPSI occurred more than 72 hours ago. • Known allergy / hypersensitivity to progestogen or to any component of the product - see summary of product characteristics (SPC). • Active acute porphyria. • Severe hepatic impairment. • Known or suspected 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. • Less than 21 days after childbirth. • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).
Cautions (including any relevant action to be taken)	• Refer to the current version of the UK Medical Eligibility Criteria for Contraceptive use (UKMEC; http://ukmec.pagelizard.com/2016) and where necessary explain the benefits and risks. • 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 acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Consider ulipristal if the individual presents in the five days leading up to estimated day of ovulation. • Levonorgestrel is ineffective if taken after ovulation. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them - see dose frequency section. • 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

[1] Although there is potential for a false negative test result where fertilisation occurred less than 3 weeks previously, the Faculty of Sexual and Reproductive Health (FSRH) recommends that levonorgestrel 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 (>72 hours), as there is no evidence to indicate levonorgestrel is not safe in pregnancy. Please note in this PGD use is only allowed within the treatment window of ≤72 hours.

	as the most effective method of EC. If levonorgestrel is to be given, see dosage section. • 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 levonorgestrel 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. • If the individual has not yet reached menarche consider referral for further assessment or investigation.
Action to be taken if the individual is excluded	• Explain the reasons for exclusion to the individual and document in the consultation record. • 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.
Action if individual or carer declines treatment	• Inform individual /carer re risks of not receiving treatment compared to the benefits. • Record reason for decline in the consultation record. • 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.

3. Description of treatment

Name, strength & formulation of drug	Levonorgestrel 1500 microgram tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
Presentation	Oral tablet
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Legal category	P/POM
Black Triangle▼	No
Unlicensed / off label use	This PGD includes off-label use in the following conditions: • Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg. • Increased dose in individuals using liver enzyme inducing agent • Individuals with previous ectopic pregnancy. Check product SPC to identify off-label usage as this can vary between manufacturers. 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 of administration	Oral
Dose and frequency	• One tablet (1500micrograms) to be taken as a single dose as soon as possible and no later than 72 hours after UPSI. • If the patient is taking (or taken within the last 28 days) enzyme-inducing medication or herbal products or has a BMI > 26 kg/m^2 or a weight > 70 kg, the dosage should be increased to TWO tablets (3000 micrograms). This should be taken as a single dose as soon as possible and no later than 72 hours after UPSI. • If vomiting occurs within three hours of taking levonorgestrel, another dose can be supplied and should be taken immediately, but this must fall within the 72 hours since UPSI occurred.
Quantity to be administered and/or supplied	• Appropriately labelled pack of one tablet. • Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m^2 or who weigh more than 70kg. • Patients should be observed taking the medication unless they are breast feeding, when they can be allowed to take the dose away for later consumption if necessary, but this must occur within the 72 hour window.

	NB. In the event of 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 72 hours of UPSI or potential contraception failure when taking away.
Maximum or minimum treatment periods	Single episode of treatment which may be repeated in the same cycle if appropriate. Please note: • If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal). • If within 5 days of ulipristal then levonorgestrel cannot be offered.
Disposal	All waste must be disposed of in accordance with the relevant waste regulations.
Drug interactions2	• 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 Patient Group Direction is appropriate. For drug interactions see BNF (https://bnf.nice.org.uk/) or the SPC (http://www.medicines.org.uk/emc/) or refer to Clinical Guidance: Drug Interactions with Hormonal Contraception . • In case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is supplied. • If the requirements of this Patient Group Direction cannot be complied with, the patient must be referred to a suitable prescriber.
Identification & management of adverse reactions2	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/ For the most common adverse effects see the table below.

Very common adverse effects (≥ 1/10)	**Common adverse effects (≥ 1/100 to <1/10)**
Headache	Dizziness
Nausea Lower abdominal pain	Diarrhoea Vomiting
Bleeding not related to menses*	Delay of menses more than 7 days ** Irregular menstruation Breast tenderness
Fatigue	

[2] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

	* Bleeding patterns may be temporarily disturbed; however 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 levonorgestrel, the possibility of an ectopic pregnancy should be considered. Abdominal pain is one of the symptoms of ectopic pregnancy. 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).

4. Records

Records	The pharmacist must make an entry for each patient on the **PharmOutcomes** system and complete all mandatory entries as required by the service specification and this PGD. The minimum required information to be collected is: • 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 • Patient's name, address, date of birth • Contact details of GP (if registered) • Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight • Name of the medication supplied • Dose, form and date of supply • Quantity, batch number and expiry date • Advice given to patient (including side effects and self-care) • Significant information e.g. if used off licence reason why • Name of pharmacist who supplied the medication • Details of any adverse drug reaction and actions taken • Any known drug allergies • Any referral arrangements made • Advice given, including advice given if excluded or declines treatment • Record refusal of treatment by pharmacist if the individual does not meet the inclusion criteria • Significant information e.g. if used off licence reason why • Record if the treatment is taken away from the pharmacy *As per SPS Retention of Pharmacy Record and SPS Retaining PGD documentation:* PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 26th birthday or for 8 years after a child's death. • *Data must be stored in accordance with Caldicott guidance, the Data Protection Act and the General Data Protection Regulation.*

5. Patient Information

Written information to be given to the patient or carer	The patient/carer should be given the following written information if appropriate: • The product specific patient information leaflet supplied with the medicine. • Provide a copy of the Family Planning Association (FPA) leaflet 'Your guide to emergency contraception' (available at

	https://www.fpa.org.uk/professionals/resources/leaflet-and-booklet-downloads) to patients.
Advice to be given to the patient or carer	The patient/carer should be given the following information verbally if appropriate and requested: • All methods of emergency contraception should be discussed. • Advise women that the Cu-IUD is the most effective method of EC if fitted within five days of UPSI or within five days from the earliest estimated ovulation. • Advise women that first line ulipristal acetate for emergency contraception has been demonstrated to be more effective than second line levonorgestrel for emergency contraception.
Advice to be given to the patient or carer	• EC providers should advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. • Effectiveness of method depends on length of time from UPSI / potential contraceptive failure to treatment. • Beneficial effects, side effect and risks should be discussed. • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • 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 levonorgestrel correctly, preferably as an immediate dose in the pharmacy. • As levonorgestrel is secreted into breast milk, breast feeding mothers may be allowed to take away levonorgestrel with them to allow them to feed their child before taking. This should only occur if it fits within the allowed time limits. They can also avoid breastfeeding for a further 8 hours after taking. There is limited evidence available which indicates that levonorgestrel has no adverse effects on breastfeeding or on the breastfed infants. • If vomiting occurs within three hours of taking, a repeat dose is required, but must be given within the 72 hours since UPSI. • Refer to Sexual Health Clinic or GP if no / light period 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. • 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 including Quick Starting Contraception guidance (recommending starting contraception immediately after oral emergency hormonal contraception 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, CG 30, updated July 2019. • Encourage use of condoms and reinforce the safer sex message. • Recommend sexually transmitted infections (STI) 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 that they should use an additional contraceptive method for 7 days (2 days for Progestogen Only Pill; 9 days for *Qlaira*®) • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. • Advise to patient taking (or taken within the last 28 days) enzyme-inducing medication or herbal products or has a BMI > 26 kg/m^2 or a weight > 70 kg on the need for an increased dose of levonorgestrel to 3000microgram (two tablets).

6. References used to develop this PGD

References

1. Faculty of Sexual and Reproductive Healthcare (FSRH) ,Standards and guidance

- FSRH Guideline - Emergency Contraception, March 2017 (amended December 2020).
- FSRH Clinical Guideline: Quick Starting Contraception (April 2017)
- FSRH Clinical Guideline: Contraceptive Choices for Young People., March 2010 (updated May 2019)
- FSRH CEU Guidance: Drug Interactions with Hormonal Contraception, May 2022

2. UK Medical Eligibility Criteria for Contraceptive Use (UKMEC 2016, amended September 2019)) Manufacturer's Summaries of Product Characteristics (SPCs)

- Levonelle® 1500microgram tablet, Bayer plc, date of last revision of the text 02/07/2021, accessed via electronic medicines compendium (eMC) on the 09/06/2023
- Levonorgestrel 1.5mg tablet, Lupin (UK) Ltd., date of last revision 01/09/2021, accessed via eMC on the 09/06/2023
- Upostelle® 1500 microgram tablet, Gedeon Richter (UK) Ltd., date of last revision 19/01/2021, accessed via eMC on the 09/06/2023

3. General Pharmaceutical Council.

- Standards for pharmacy professionals, May 2017.
- Guidance on maintaining clear sexual boundaries, revised February 2020
- Guidance on patient confidentiality, June 2018.
- In practice: Guidance on consent, revised June 2018.

4. Centre for Pharmacy Postgraduate Education (CPPE)

- Declaration of competence for pharmacy services; Emergency Contraception Service with the use of a Patient Group Direction. Version 23 (August 2022)

5. NHS England
- Records Management: Code of Practice for Health and Social Care, July 2016 (last updated August 2021)
6. Specialist Pharmacy Service (SPS)
- Recommendations for the Retention of Pharmacy Records January 2021
- Retaining legal mechanism documentation, June 2021 (last updated April 2023)
- Supply and administration of levonorgestrel 1500 micrograms tablets for emergency contraception: PGD template, v2.0, March 2023

7. BNF online
8. Hayley Willacy, Ectopic Pregnancy, Last edited May 2021, accessed via patient.info
9. NICE CKS, Ectopic pregnancy, Last revised December 2022

Appendix A - Pharmacist authorisation sheet

Levonorgestrel EC PGD Version 6.0 Valid from: 31/08/2023 Expiry: 30/08/2025

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

Pharmacist

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 pharmacists 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 pharmacists 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 pharmacists to prevent additions post managerial authorisation.

A copy of this PGD with completed pharmacist authorisation sheet should be retained and available at the pharmacy premises as a record of those pharmacists authorised to work under this PGD.