This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practise under it. The most recent and in date final signed version of the PGD should be used.

# PATIENT GROUP DIRECTION (PGD)

## For the Supply of a progestogen only contraceptive pill (POP) by registered nurses and midwives in BPAS clinics.

## Version Number 2.1

| Change History | |
|---|---|
| Version and Date | Change Details |
| Version 1<br>April 2020 | New template. *Approved for use in BPAS 04/11/20.* |
| Version 1.1<br>November 2020 | Minor rewording and highlighting of contents cautions section relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan. Porphyria added as exclusion criteria. *Version not used in BPAS* |
| Version 2.0<br>April 2023 | Updated template – amended references, minor editing and working changes/clarifications.<br>Addition by BPAS of information to provide to client in the event POP supplied ahead of abortion treatment and client chooses to continue with pregnancy. *Approved for use in BPAS 27/03/23.* |
| Version 2.1<br>April 2024 | Revised content with drospirenone information now UK product is available. Expanded on other POP active ingredients to distinguish. *Not available on BPAS formulary – not included.* Added note re low risk of breast cancer. Updated references. Updated SLWG. |

Valid from: 01/08/2024

Review Date: September 2025

Expiry Date: 31 March 2026

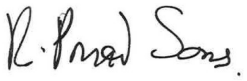
*N.B. Review and update may occur prior to this period if national guidance changes or legal or clinical issues arise.*

## BPAS PGD Organisational Authorisations:

This PGD is not legally valid until it has had the relevant organisational authorisations below.

| Name | Job title and organisation | Signature | Date |
|---|---|---|---|
| Mary Sexton | BPAS Clinical Director |  | 19/08/2024 |
| Dr Julie Miller | BPAS Medical Director |  | 16/08/2024 |
| Kalpesh Thakrar | BPAS Lead Pharmacist |  | 30/07/2024 |

Authorising Body:

| | | | |
|---|---|---|---|
| *Cheshire and Merseyside ICB* | *Rowan Pritchard-Jones* |  | *07/11/2024* |

**Responsible person who has approved this PGD on behalf of BPAS**

Name: Heidi Stewart

Position: BPAS Chief Executive

Signature: 

Date: 22/08/2024

| Glossary | |
|---|---|
| BPAS | British Pregnancy Advisory Service |
| BLS | Basic life support |
| BNF | British National Formulary |
| FSRH | Faculty of sexual and reproductive health |
| IUD | Intrauterine device |
| LARC | Long-acting reversible contraception |
| LNG-IUD | Levonorgestrel intrauterine device |
| MHRA | Medicines Health Regulatory Agency |
| NICE | National Institute for Health and Care Excellence |
| NMC | Nursing and Midwifery Council |
| POP | Progesterone only contraceptive pill |
| SmPC | Summary of medicinal product characteristics |
| STI | Sexually transmitted infection |
| TTO | To take out |

## PGD DEVELOPMENT GROUP

| | |
|---|---|
| Date PGD template comes into effect: | April 2023 |
| Review date: | September 2025 |
| Expiry date: | March 2026 |

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2022.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

| Name | Designation |
|---|---|
| Dr Cindy Farmer | Vice President, General Training<br>Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michelle Jenkins | Advanced Nurse Practitioner, Clinical Standards Committee<br>Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Vicky Garner | Deputy Chief Midwife British Pregnancy Advisory Service (BPAS) |
| Julia Hogan | Clinical Nurse Specialist |
| Kate Devonport | National Unplanned Pregnancy Advisory Service (NUPAS) |
| Chetna Parmar | Pharmacist adviser Umbrella |
| Heather Randle | Royal College of Nursing (RCN) |
| Carmel Lloyd | Royal College of Midwives (RCM) |
| Clare Livingstone | Royal College of Midwives (RCM) |
| Kirsty Armstrong | National Pharmacy Integration Lead, NHS England |
| Dipti Patel | Local authority pharmacist |
| Emma Anderson | Centre for Pharmacy Postgraduate Education (CPPE) |
| Alison Crompton | Community pharmacist |
| Lisa Knight | Community Health Services pharmacist |
| Bola Sotubo | NHS North East London ICB pharmacist |
| Sim Sesane | CASH Nurse Consultant, MSI Reproductive Choices |
| Portia Jackson | Lead Pharmacist iCaSH, Cambridgeshire Community Services |
| Tracy Rogers | Director, Medicines Use and Safety, Specialist Pharmacy Service |
| Sandra Wolper | Associate Director Specialist Pharmacy Service |
| Jo Jenkins | Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service |
| Rosie Furner (Working Group Co-ordinator) | Specialist Pharmacist – Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service |

| 1. Characteristics of staff authorised to use this PGD: | |
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| **Qualifications and professional registration** | • NMC Registered Nurse<br>• NMC Registered Midwife<br><br>With a current contract of employment with BPAS<br><br>Practitioners must also fulfil the additional requirements listed below. |
| **Initial training** | Pharmacological knowledge relating to the administration and supply of the medicine, its uses, contraindications, dosage and adverse effects<br><br>Additionally, practitioners:<br>• Must have completed appropriate training for working under a PGD for the supply / administration of medicines (see training requirements in the BPAS PGD policy). Recommended training - eLfH PGD elearning programme<br>• Must be familiar with the medicine and observant to changes in the BNF and Summary of Product Characteristics (SmPC)<br>• Must be competent in the recognition and management of adverse reactions, including anaphylaxis<br>• Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum<br>• Must have access to the PGD and associated online resources<br>• Must have completed FSRH 'Essential Contraception for Abortion Care Providers' training or equivalent<br>• Must have completed required BPAS training (including updates) in safeguarding children and vulnerable adults<br><br>**The practitioner must be authorised by name, under the current version and terms of this PGD in the Approved Practitioner List before working to it.** |
| **Competency Assessment** | Practitioners working under this PGD are required to review their own competency using the NICE Competency Framework for Health Professionals using Patient Group Directions<br><br>Practitioners working under this PGD must be assessed as competent or complete a self-declaration of competence to use this PGD (see appendix A).<br><br>**Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.** |
| **Ongoing training and competency** | • Practitioners must complete 3-yearly PGD Theory Refresher training and competency assessment<br>• Practitioners working under this PGD are responsible for ensuring they remain up to date with the use of the medicines and guidance included in the PGD, ensuring any training needs identified are addressed with further training<br>• Practitioners must make sure they are aware of any changes to the recommendations for this medication |

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| | • Practitioners must ensure they remain up to date with relevant clinical skills, management of anaphylaxis, BLS (as a minimum), with evidence of continued professional development<br>• Practitioners are responsible for maintaining their competency to work under this PGD |
| *The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policy.* | |

| ***2. Clinical condition or situation to which this PGD applies:*** | |
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| **Clinical condition or situation to which this PGD applies** | Contraception |
| **Inclusion criteria** | • Individual (age from menarche to 55 years) presenting for contraception<br>• Consent given. |
| **Exclusion criteria** | • Individuals not suitable for treatment at BPAS *(N.B. please refer to BPAS suitability criteria)*<br>• Consent not given<br>• Individuals under 16 years of age and assessed as not competent using Fraser Guidelines<br>• Individuals 16 years of age and over and assessed as lacking capacity to consent<br>• Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics<br>• Individuals using enzyme-inducing medicines/herbal products or within 4 weeks of stopping them.<br>• Acute porphyria *(N.B. porphyria is a contraindication to treatment at BPAS – please refer to the BPAS suitability criteria)*<br><br>**Cardiovascular Disease**<br>• Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic first attack only if taking the method when the event occurred.<br><br>**Cancers**<br>• Current or past history of breast cancer<br>• Malignant liver tumour (hepatocellular carcinoma)<br><br>**Gastro-intestinal conditions**<br>• Severe decompensated cirrhosis<br>• Benign liver tumour (hepatocellular adenoma<br>• Any bariatric or other surgery resulting in malabsorption.<br><br>**Medicines**<br><br>Individuals taking any interacting medicines (other than enzyme inducers), including medicines purchased – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk |
| **Cautions/Circumstances in which further advice should be sought (including any relevant action to be taken)** | • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented<br>• If the individual is less than 13 years of age, the healthcare professional should speak to local safeguarding lead and refer to the BPAS Safeguarding and Management of Clients Aged under 18 policy |

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| | • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain<br>• 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 POP is not contra-indicated it may be less effective and so these individuals should be advised offered Long-Acting Reversible Contraception (LARC)<br>• Individuals should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness of POP<br>• Offer LARC to all individuals in particular those with medical conditions for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan<br>• If an individual is known to be taking a medication which is known to be harmful to pregnancy a highly effective form of contraception is recommended. Highly effective methods include the LARC methods: copper IUD, LNG-IUD and implant. If a LARC method is unacceptable/unsuitable and a POP is chosen, then an additional barrier method of contraception is advised. See FSRH advice |
| **Action to be taken if the individual is excluded or declines treatment** | • Explain the reasons for exclusion to the individual and document in the consultation record<br>• Record reason for declining treatment in the consultation record<br>• Where appropriate refer the individual to a suitable health service provider and/or provide them with information about further options |
| **Arrangements for referral for medical advice** | • Inform and discuss with the doctor in clinic. If not available, discuss with a regional clinical director<br>• In the event of a medical emergency, e.g. anaphylaxis, provide immediate care in line with UK Resuscitation Council guidance, dial 999 to summon a paramedic response and initiate emergency transfer to NHS care<br>• Document findings/action taken in individual's record |

| ***3. Description of treatment:*** | |
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| **Name, strength and formulation medicine** | • Desogestrel 75micrograms tablets<br>• Levonorgestrel 30micrograms tablets<br>• Norethisterone 350micrograms tablets<br><br>Note:<br>• The above names the generic component of available progestogen only contraceptive pills.<br>• This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to.<br>• Some desogestrel products contain excipients containing soya/nut – awareness of allergy may be required depending on product offered.<br>• See http://www.mhra.gov.uk/spc-pil/ or http://www.medicines.org.uk for further information and further brand information including full details of adverse effects and interactions. |

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| **Legal category** | POM |
| **Route / method of administration** | Oral |
| **Indicate any off-label use (if relevant)** | Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SmPC).<br><br>This PGD includes inclusion criteria, exclusion criteria and dosage regimens which are outside the market authorisation for many of the available products, but which are included within FSRH guidance.<br><br>Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management.<br><br>Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence. |
| **Dose and frequency of administration** | • Single tablet taken at the same time each day starting on day 1-5 of the menstrual cycle with no need for additional protection<br>• The POP can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional precautions are then required for 48 hours after starting and advise to have follow up pregnancy test at 21 days<br>• When starting or restarting the POP as quick start after levonorgestrel emergency contraception, additional contraception is required for 48 hours<br>• In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective<br>• For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines |
| **Duration of treatment** | • For as long as the individual requires POP and has no contraindications to the use of POP |
| **Total quantity to be administered or quantity to be supplied as TTO** | • Up to three months' supply in pre-labelled TTO pack(s) |
| **Storage** | Stock must be securely stored in accordance with the BPAS Medicines Management policy and in conditions in line with the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk |
| **Drug interactions** | All concurrent medications, including those purchased should be considered for interactions.<br><br>A detailed list of drug interactions is available in the individual product SmPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and FSRH CEU |

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| | Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ |
| **Identification and management of adverse reactions** | A detailed list of adverse reactions is available in the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org<br><br>The following possible adverse effects are commonly reported with POP (but may not reflect all reported adverse effects):<br>• Acne<br>• Breast tenderness<br>• Headache<br>• Disturbance of bleeding patterns<br>• Changes in mood/libido<br>• Weight change<br><br>This list may not represent all reported side-effects of this medicine. Refer to the most current SmPC for more information.<br><br>If necessary, seek appropriate emergency medical advice and assistance. |
| **Management and reporting procedure for adverse reactions** | Document any adverse drug reactions (ADRs) in the individual's clinical records. If necessary, seek appropriate emergency medical advice and assistance as clinically indicated.<br><br>Suspected ADRs are encouraged to be reported to the MHRA via https://yellowcard.mhra.gov.uk/<br><br>Adverse drug reactions must also be reported via Datix, including drug name, strength, formulation, batch numbers and expiry dates. |
| **Written information and further advice to be given to the individual or carer** | • Provide manufacturer's information leaflet (PIL) provided within the original pack<br>• Individuals should be informed about the superior effectiveness of LARC<br>• Explain mode of action, side effects, and benefits of the medicine.<br>• Advise on action if the individual vomits within two hours of taking the pill or in cases of prolonged vomiting or severe diarrhoea. See FSRH guidance<br>• Advise on missed pills (missed pills; twelve hours after normal administration time for desogestrel; three hours after normal administration time for all other POPs). See FSRH guidance<br>• Advise on risks of the medication including failure rates, serious side effects and the actions to be taken<br>• Advise that risk of any pregnancy is low during use of effective contraception. Of pregnancies that occur during use of the traditional POP, 1 in 10 may be ectopic<br>• Individuals should be advised that current use of progestogen-only contraceptives is associated with a small increased risk of breast cancer which reduces with time after stopping.<br>• Where POP is supplied ahead of abortion treatment, advise client that if they choose to continue with their pregnancy, the contraception should not be started. If abortion treatment failure occurs after starting the POP and a decision to continue the pregnancy is made, it should be stopped. The BPAS unit should be informed, and any unused POP should be returned to a BPAS unit or pharmacy for disposal |

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| | • A follow up review should be undertaken annually with GP or sexual and reproductive health services<br>• Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs)<br>• Ensure the individual has the contact details of local sexual health services<br>• Advise the individual to seek advice from a pharmacist, doctor or other prescriber before starting any new medications, including those purchased<br>• Offer Relevant BPAS client information booklet relevant to their treatment, including Aftercare information |
| **Follow-up advice to be given to the individual or carer** | • Inform the individual/carer of possible side effects and their management<br>• The individual should be advised to seek medical advice in the event of an adverse reaction<br>• The individual should seek further advice if they have any concerns<br>• Review annually with GP or sexual and reproductive health services |
| **Records to be kept** | The following must be recorded in the client records in line with the NMC Code and BPAS' Record Keeping policy, using black ink if written:<br>• The consent of the individual and<br>  ○ If individual is under 13 years of age record action taken<br>  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.<br>  ○ If individual over 16 years of age and not competent, record action taken<br>• Name of individual, address, date of birth<br>• GP contact details where appropriate<br>• Relevant past and present medical history, including medication and family history.<br>• Examination finding where relevant<br>• Any known allergies<br>• Name of registered health professional<br>• Name of medication supplied<br>• Date of supply<br>• Dose supplied<br>• Quantity supplied, including batch number and expiry date<br>• Advice given, including advice given if excluded or declines treatment<br>• Details of any adverse drug reactions and actions taken<br>• Advice given about the medication including side effects, benefits, and when and what to do if any concerns<br>• Any referral arrangements made<br>• Any supply outside the terms of the product marketing authorisation<br>• Recorded that supply is via Patient Group Direction (PGD)<br><br>Records should be signed and dated (or password controlled e-records) and securely kept for the defined period as specified in the BPAS PGD policy.<br><br>All records should be clear, legible and contemporaneous.<br><br>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with the BPAS PGD policy. |

## 4. References and other source material:

- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2
- Faculty of Sexual and Reproductive Health Clinical Guideline: Progestogen-only Pills August 2022 https://www.fsrh.org/standards-and-guidance/documents/cec-guideline-pop/
- FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) - Faculty of Sexual and Reproductive Healthcare
- Faculty of Sexual and Reproductive Healthcare (2019, amended November 2020) Combined Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/
- Faculty of Sexual and Reproductive Healthcare (2016, amended 2019) UK Medical Eligibility Criteria for Contraceptive Use.
- https://www.fsrh.org/documents/ukmec-2016/
- Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/
- Faculty of Sexual and Reproductive Healthcare (2023) Response to new study on use of combined and progestogen-only hormonal contraception and breast cancer risk. FSRH Response to new study on use of CHC and POC and breast cancer risk (March 2023) - Faculty of Sexual and Reproductive Healthcare
- NICE, 2017. Medicines practice guideline Patient Group Directions www.nice.org.uk/guidance/mpg2
- UK Resuscitation Council, 2021. Adult basic life support Guidelines | Resuscitation Council UK

## 5. Audit and ongoing monitoring of this PGD

Please refer to the ‘Audit’ section of the BPAS Patient Group Direction policy for additional guidance in relation to PGD audit.

The PGD audit tool is available here: British Pregnancy Advisory Service - Audit Tools - All Documents (sharepoint.com).

Units must retain a local copy of the completed audit tool as evidence.

The PGD audit criteria include:

1. Staff member has named, dated and signed the relevant PGD document
2. Client is documented as being referred to a medical practitioner if they are excluded from treatment under the PGD and there is no suitable alternative.
3. Date and time of supply / administration is on the prescription record / CAS2.
4. Client details – name, date of birth, allergies and any previous adverse effects are on the prescription record / CAS2.
5. Details of the medicine – name, strength, dose frequency, quantity, route and site (if by injection) of administration are on the prescription record / CAS2.
6. A statement that supply or administration is by using a PGD is on the prescription record / CAS2.
7. Name and signature (which may be electronic for CAS2 records) of the health professional supplying or administering the medicine is on the prescription record / CAS2.
8. Relevant information was provided to the client or their carer.
9. Client not documented to be allergic to the drug.
10. Paper documentation in related to PGDs are in black ink only.
11. Where appropriate for the medication, correct scheduling has been discussed.
12. Client does not meet any exclusions or contraindications listed in the most up to date PGD.

## Appendix A: Approved Practitioner List

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|---|---|---|
| **Patient Group Direction (PGD) name:** | Supply of a progestogen only contraceptive pill (POP) by registered nurses and midwives in BPAS Clinics v2.1. | |
| | **Valid from: 01/08/2024** | **Expiry: 31/03/2026** |

### Registered health professional

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

PGDs do not remove 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. The practitioner MUST sign this document before they can work under this PGD.

| ***I confirm that I have read and understood the contents of this PGD. I confirm that I am willing and competent to work to this PGD within my professional code of conduct.*** | | | | |
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| **Name (print)** | **Designation** | **NMC PIN** | **Signature** | **Date** |
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### 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 for the above named health care professionals who have signed the PGD to work under it.*** | | | | |
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| **Name** | **Position** | **BPAS Treatment Unit** | **Signature** | **Date:** |
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***Note to authorising manager***

- Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
- If registered health professional signatures need to be added at a later date, e.g. due to staffing changes, a separate Approved Practitioner List must be signed, ensuring the correct PGD name and version is detailed.
- This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD for the period specified in the BPAS PGD policy.
- This list must be stored by the Treatment Unit in a designated folder and be available for immediate inspection, alongside any training / competency records. If a registered professional works across multiple sites, they must sign the Approved Practitioner List for each PGD at each BPAS site where they will use the PGD.