PATIENT GROUP DIRECTION (PGD)

Supply of a progestogen only contraceptive pill (POP) by Community Pharmacists in England working in a pharmacy registered to provide the NHS Pharmacy Contraception Service Pilot

Version 2.0

Change History	
Version and Date	**Change details**
Version 1 April 2020	New template
Version 1.1 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 2.0 April 2023	Updated template – amended references and minor editing and wording changes/clarifications.

Version: 2.0

Valid from: 1st April 2023

Review date: September 2025

Expiry date: 31st March 2026

This Patient Group Direction (PGD) must only be used by pharmacists who have been named and authorised by their organisation to practice under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

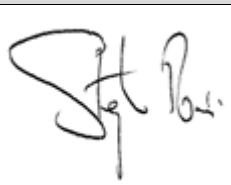
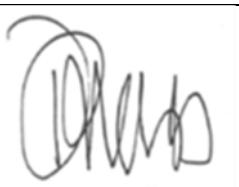
Date PGD template comes into effect:	1st April 2023
Review date	September 2025
Expiry date:	31st March 2026

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It was approved by the Faculty of Sexual and Reproductive Healthcare (FSRH) in April 2023.

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

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife, British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron, British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant, MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Advisory Service (NUPAS)
Chetna Parmar	Pharmacist adviser, Umbrella
Helen Donovan	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)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director, Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms, Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	National Medical Director, NHS England		23.03.23
Senior pharmacist **David Webb**	Chief Pharmaceutical Officer, NHS England		20.03.23
Person signing on behalf of authorising body **David Webb**	Chief Pharmaceutical Officer, NHS England		20.03.23

1. Characteristics of staff

Qualifications and professional registration	GPhC registered pharmacist able to practice under Patient Group Directions (PGDs).
Initial training	The pharmacist authorised to operate under this PGD must have undertaken appropriate education and training and be competent to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with the specification. To deliver this service, the pharmacist should have evidence of competence in the clinical skills and knowledge covered in the CPPE and/or the Health Education England e-learning for healthcare (elfh) modules listed in the service specification.
Competency assessment	• Pharmacists operating under this PGD must be assessed as competent (see Appendix A). • Pharmacists operating under this PGD are encouraged to review their competency using appropriate competency framework tools, such as the NICE Competency framework: For health professionals using patient group directions.
Ongoing training and competency	• Pharmacists operating under this PGD are personally responsible for ensuring 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 undertaken, as required.
The decision to supply any medication rests with the individual pharmacist who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• This PGD applies to the pilot NHS Pharmacy Contraception Services only:
	  ○ Tier 1 - Review and ongoing supply of oral contraception where previously initiated in primary care or sexual health clinics (or equivalent).
	  ○ Tier 2 – Initiation of oral contraception.

Criteria for inclusion	• Individual (age: from menarche up to and including 54 years) presenting for an ongoing supply of their oral contraception. •
Criteria for exclusion	• Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Established pregnancy. Note – risk of pregnancy with a negative pregnancy test is not an exclusion. • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics (SPC). • Acute porphyria. • Individuals aged 55 years and over. **Cardiovascular Disease** • Current or past history of ischemic heart disease, vascular disease, stroke, or transient ischemic attack (first attack only) if taking the method when the event occurred. **Cancers** • Current or past history of breast cancer. • Malignant liver tumour (hepatocellular carcinoma). **Gastro-intestinal conditions** • Severe (decompensated) cirrhosis. • Benign liver tumour (hepatocellular adenoma). • Any bariatric or other surgery resulting in malabsorption. **Medicines** • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them.

	• Individuals taking any interacting medicines (other than enzyme inducers) including medicines or herbal products purchased – see, current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk.
Cautions 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. • If the individual is less than 13 years of age, the pharmacist should speak to the local safeguarding lead and follow the local safeguarding policy. • If there are reasons to believe an individual aged 16 or over lacks capacity, an assessment of capacity to consent should be conducted and recorded in their notes. Particular consideration should be given to any concern of sexual assault or sexual violence in vulnerable adults. • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the pharmacist is unsure or uncertain. • 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 contraindicated, it may be less effective and so these individuals should be advised to consider Long-Acting Reversible Contraception (LARC). • 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. • **The option of LARC should be discussed with all individuals, in particular those with medical conditions for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan. If this option is accepted, individuals should be signposted to where they can access LARC.** • **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: IUD, IUS, 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. • Record reason for declining treatment in the consultation record. • Where required, refer the individual 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	• **See Appendix B** • This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to. • Some desogestrel products contain excipients containing soya/nut – awareness of allergy may be required depending on product offered. • 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.
Legal category	POM
Route of administration	Oral
Off label use	Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the SPC.This PGD includes inclusion criteria and exclusion criteria which are outside the market authorisation for many of the available products, but which are included within FSRH guidance. Medicines should be stored according to the conditions detailed in the manufacturers' guidelines. However, in the event of an inadvertent or unavoidable deviation of these conditions, the Responsible Pharmacist must be consulted. Where medicines have been assessed by the Responsible Pharmacist 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 the Responsible Pharmacist. Where a medicine is recommended for off-label use, 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. • 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. • When starting or restarting the POP as quick start after levonorgestrel emergency contraception, additional contraception is required for 48 hours. • 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. • 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, meets the inclusion criteria, and has no contraindications to the use of POP.
Quantity to be supplied	• Tier 1 Ongoing supply - **Supply up to twelve months** in appropriately labelled original packs. • Tier 2 Initiation - **Supply up to three months** in appropriately labelled original packs.
Drug interactions	All concurrent medications and herbal products, including those purchased should be considered for interactions. A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/.
Identification & management of adverse reactions	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 www.bnf.org. The following possible adverse effects are commonly reported with POP (but may not reflect all reported adverse effects): • Acne • Breast tenderness • Headache

	• Disturbance of bleeding patterns • Changes in mood/libido • Weight change
Management of and reporting procedure for adverse reactions	• Record all adverse drug reactions (ADRs) in the patient's medical record. • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk.
Management of and reporting procedure for patient safety incidents	• The pharmacy is required to report any patient safety incidents in line with the https://www.gov.uk/government/publications/clinical-governance-approved-particulars.
Written information and further advice to be given to individual	• Provide a patient information leaflet (PIL) with the original pack. • Individuals should be informed about the superior effectiveness of LARC. • Explain mode of action, side effects, and benefits of the medicine. • 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. • Advise on missed pill advice (missed pills; twelve hours after normal administration time for desogestrel; three hours after normal administration time for all other POPs). See FSRH guidance. • Advise on risks of the medication, including failure rates and serious side effects and the actions to be taken. • 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. • Recommend the use of condoms and offer advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs), where appropriate. • Ensure the individual has contact details of any appropriate local services/sexual health services. • Advise the individual to seek advice from a pharmacist, doctor, or other prescriber before starting any new medications or herbal products, including those purchased.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should seek further advice if they have any concerns. • The individual should be advised on how to obtain future supplies.

Records	**Record:**
	• 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 is 16 years of age or over 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 and family history.
	• Any known allergies.
	• Name and registration number of pharmacist.
	• Name of medication supplied.
	• Date of supply.
	• Dose amount.
	• 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 supply is via PGD.
	
	Records should be signed and dated (or be a password-controlled e-record) and securely kept for a defined period in line with the specification.
	
	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 the specification.

4. Key references

Key references (accessed March 2020)	• 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 • Fraser guidelines https://learning.nspcc.org.uk/child-protection-system/gillick-competence-fraser-guidelines#skip-to-content • FSRH Clinical Guideline: Progestogen-only Pills (August 2022, Amended November 2022) https://www.fsrh.org/standards-and-guidance/documents/cec-guideline-pop/ • FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • FSRH Clinical Guideline: Combined Hormonal Contraception (January 2019, Amended November 2020) https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/ • FSRH UK Medical Eligibility Criteria for Contraceptive Use. (April 2016, Amended 2019) 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/fsrh-guidelines-and-statements/quick-starting-contraception/

Appendix A – Registered pharmacist authorisation sheet

PGD progestogen only contraceptive pill (POP) Version 2.0

Valid from: 1st April 2023 **Expiry: 31st March 2026**

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

Registered pharmacist

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

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each pharmacist 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 PGD 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.

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

Appendix B – Name, strength & formulation of drug

VMP/AMP Name	VMP/AMP Snomed Code	VMPP/AMPP Snomed Code	Supplier Name
Desogestrel 75microgram tablets	**400419002**	**3410511000001107**	
Cerazette 75microgram tablets	3411311000001106	3411611000001101	Organon Pharma (UK) Ltd
Cerelle 75microgram tablets	22263411000001107	22263511000001106	Consilient Health Ltd
Desogestrel 75microgram tablets	21695811000001107	21695911000001102	Alliance Healthcare (Distribution) Ltd
Desogestrel 75microgram tablets	21732311000001109	21732411000001102	A A H Pharmaceuticals Ltd
Desogestrel 75microgram tablets	23968111000001101	23968211000001107	DE Pharmaceuticals
Desogestrel 75microgram tablets	29760711000001107	29760811000001104	Zentiva Pharma UK Ltd
Desogestrel 75microgram tablets	29802211000001102	29802411000001103	Sigma Pharmaceuticals Plc
Desogestrel 75microgram tablets	34551611000001104	34551711000001108	Crescent Pharma Ltd
Desogestrel 75microgram tablets	35102211000001103	35102311000001106	Lupin Healthcare (UK) Ltd
Desogestrel 75microgram tablets	38829211000001101	38829311000001109	Morningside Healthcare Ltd
Desogestrel 75microgram tablets	38867011000001109	38867111000001105	Medihealth (Northern) Ltd
Desomono 75microgram tablets	22502911000001100	22503011000001108	MedRx Licences Ltd
Desorex 75microgram tablets	21706911000001101	21707011000001102	Somex Pharma
Feanolla 75microgram tablets	24677711000001105	24677811000001102	Lupin Healthcare (UK) Ltd
Moonia 75microgram tablets	36546611000001102	36547111000001108	Stragen UK Ltd
Zelleta 75microgram tablets	23269711000001105	23269811000001102	Morningside Healthcare Ltd
Levonorgestrel 30microgram tablets	**326425002**	**982011000001106**	
Norgeston 30microgram tablets	221011000001108	1930011000001102	Bayer Plc
Norethisterone 350microgram tablets	**326447002**	**1313211000001103**	
Noriday 350microgram tablets	167411000001104	1843411000001105	Pfizer Ltd