NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Progestogen Only Contraceptive Pill (POP) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from FSRH/SPS and Patient Group Direction (PGD) Supply of a progestogen only contraceptive pill (POP) version 2.2 – Date Published April 2025		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/POP/ MGPG1351	**Review Date:** September 2025 **Expiry Date:** March 2026	**Date Approved:** May 2025

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2.2 (Amended April 2025)

Revision History for NoS:

NoS PGD that has been adapted and/or superseded	PGD supersedes NOS/PGD/POP/MGPG1120, Version 2	
Date of change	**Summary of Changes**	**Section heading**
	SPS version 2.1 was unpublished by NoS	
September 2024	Transferred onto new national template	
September 2024	Reference to NoS Appendix 1 and 2	Authorisation
September 2024	Removed SPS advised training and added TURAS NoS PGD training link added	Initial Training
September 2024	Added in statement about capacity under the age of 13 and the legislation statement added	Criteria for inclusion
September 2024	NICE Competency framework statement removed	Competency assessment
September 2024	Added clinical systems utilised.	Records
September 2024	HEPMA added.	Records
September 2024	Statement added about supply and over labelled stock	Legal category
October 2024	All reference to drospirenone removed from PGD as not recommended for use in Scotland	Throughout
April 2025	Updated as per SPS version 2.1 and 2.2	
May 2025	Title changed in keeping with SPS version	

FSRH/SPS most recent changes

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 2.1 April 2024	Revised content with drospirenone information now UK product is available. Expanded on other POP active ingredients to distinguish. Added note re low risk of breast cancer. Updated references. Updated SLWG.
Version 2.2 April 2025	Added statement on advice when used in combination with GLP-1 agonists. Updated references.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by SPS/FSRH and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Heike Gleser	Signature		Date Signed	06/05/2025
Pharmacist	Alison Jane Smith	Signature		Date Signed	07/05/2025
Nurse	Sarah Jane Walton	Signature	Sarah Walton	Date Signed	01/05/2025

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		14/05/2025

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Interim Chief Executive – Adam Coldwells		15/05/2025

Version 2.2 – Approved for NoS from 15th May 2025.

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, Professional Learning and Development Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Consultant 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

Characteristics of staff

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with local policy. Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory. Have undertaken NoS PGD module training on TURAS Learn. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults, or level 2 safeguarding for adults and children, or equivalent
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix 1) or complete a self-declaration of competence for contraception supply.
Ongoing training and competency	• Individuals 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 provided. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Contraception
Criteria for inclusion	• Norethisterone, levonorgestrel and desogestrel - Individual (age from menarche to 55 years) presenting for contraception. • Aged 13 years and over. All individual under the age of 18 years - follow local young person's risk assessment or equivalent local process. • Individuals under 16 years of age may give consent for the supply of POP, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment'. • Consent given.
Criteria for exclusion	• Consent not given. • 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 • Acute porphyria **Cardiovascular Disease** • 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.

	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 medicines/herbal products or within 4 weeks of stopping them. • 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 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 healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional 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 contra-indicated it may be less effective and so these individuals should be advised offered 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, GLP-1 agonists) could reduce the effectiveness of POP. • Individuals receiving GLP-1 agonists must use effective contraception. Note some GLP-1 agonists may reduce the effectiveness of oral contraception and additional barrier methods are recommended - refer to SmPC and FSRH advice regarding GLP 1 agonists and contraception. Provide FSRH patient information leaflet (PIL).

	• **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.** • **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. • Record reason for declining treatment in the consultation record. • Where appropriate refer the individual to a suitable health service provider and/or provide them with information about further options.

Description of treatment

Name, strength & formulation of drug	• Desogestrel 75micrograms tablets • Levonorgestrel 30micrograms tablets • Norethisterone 350micrograms tablets Note: • The above names the generic component of available progestogen only contraceptive pills. • 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 In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.

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 Summary of Product Characteristics (SPC). 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. 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. 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. • 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 and has no contraindications to the use of POP.
Quantity to be supplied	Supply up to twelve months in appropriately labelled original packs.
Storage	Medicines must be stored securely according to national guidelines.
Drug interactions	All concurrent medications, 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	• Healthcare professionals and individuals/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 • Record all adverse drug reactions (ADRs) in the individual's clinical record.
Written information and further advice to be given to individual	• Provide manufacturer's information leaflet (PIL) provided within 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 pills (missed pills; twelve hours after normal administration time for desogestrel; three hours after normal administration time for norethisterone and levonorgestrel POPs). See FSRH guidance. • Advise on risks of the medication including failure rates, 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. • 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. • A follow up review should be undertaken annually. • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Ensure the individual has the contact details of local sexual health services. • Advise the individual to seek advice from a pharmacist, doctor or other prescriber before starting any new medications, 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. • Review annually.
Records	**Record:** • The consent of the individual and/or o If individual is under 16 years of age document capacity using Fraser guidelines. o If individual is under 13 years of age and not competent, record action taken o If individual is under 16 years and not competent, record action taken o If individual over 16 years of age and not competent, record action taken • Name of individual, address, date of birth • GP contact details where available/appropriate • Relevant past and present medical history • Relevant medication history (to include over the counter, herbal medications, supplements and recreational drug use). • Examination or microbiology finding/s where relevant. • Any known allergies

	• Name of registered health professional • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including, dosing regimen, side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Any supply outside the terms of the product marketing authorisation • Recorded that supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate All records should be clear, legible and contemporaneous. • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Key references

Key references (accessed January 2024)	• 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) Rresponse 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 • FSRH statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception (January 2025) CEU-statement-GLP-1-agonists-and-contraception.pdf • FSRH: GLP-1 agonists and contraception Patient information leaflet (February 2025) Patient-information-GLP-1-agonists-and-contraception.pdf

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1 - Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Progestogen Only Contraceptive Pill (POP) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.2

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Progestogen Only Contraceptive Pill (POP) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.2
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Supply Of Progestogen Only Contraceptive Pill (POP) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.2					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**