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

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

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group**: See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NoS Identifier: NoS/PGD/POP/ MGPG1351	**Review Date:** February 2025 **Expiry Date:** February 2026	**Date Approved:** February 2023

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

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NoS/PGD/POP/MGPG1120, Version 1	
Date of change	**Summary of Changes**	**Section heading**
September 2022	2 yearly review of PGD incorporating the FSRH/SPS National template.	
September 2022	Acute porphyria added as per National template.	Exclusion criteria
November 2022	Some generic desogestrel products contain soya and/or peanut oil added.	Exclusion criteria
April 2023	Severe renal insufficiency or acute renal failure added	Exclusion Criteria
April 2023	Statement about renal insufficiency or treated hypoaldosteronism added	Precautions and special warnings
April 2023	Statement about Blood pressure check and U+Es prior to commencement added	Precautions and special warnings

NoS Identifier: NoS/PGD/POP/MGPG1351
Keyword(s): PGD Patient Group Direction desogestrel progestogen only contraceptive pill nurses midwives

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:	Drafted:	September 2022
	Completed:	November 2022
	Approved:	February 2023 (published – May 2023)
	Amended and re-authorised:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Heike Gleser **Health Board:** NHST **Title:** Consultant Sexual and Reproductive Health **Contact email:** heike.gleser@nhs.scot **Signature:** ..... **Date:** 16/05/2023
Senior representative of the professional group who will provide care under the direction	**Name:** Sara Beveridge **Health Board:** NHST **Title:** Clinical Nurse Specialist **Contact email:** sara.beveridge@nhs.scot **Signature:** ..... S. Beveridge ..... **Date:** 20/04/2023
Lead author	**Name:** Jodie Allan **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** jodie.allan@nhs.scot **Signature:** ..... **Date:** 15/03/2023
Pharmacist	**Name:** Alison Jane Smith **Health Board:** NHSG **Title :** Medicines Management Pharmacist **Contact email:** alisonjane.smith@nhs.scot **Signature:** ..... **Date:** 21/04/2023

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		16/03/2023

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		18/05/2023

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Jodie Allan	**Lead Author:** Medicines Management Specialist Nurse NHSG
Alison Jane Smith	**Pharmacist:** Medicines Management Pharmacist NHSG
Dr Heike Gleser	**Medical Practitioner:** Consultant Sexual and Reproductive Health NHST
Julia Penn	**Senior Representative:** Sexual Health Nurse Team Leader NHSG
Sara Beveridge	Clinical Nurse Specialist Sexual and Reproductive Health NHST
Kimberly MacInnes	Service Manager/Lead Nurse NHSH
Dr Diana Reed	Consultant in Sexual and Reproductive Health NHSG
Deborah Syme	Team Leader The Corner NHST

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to supply the desogestrel progestogen only contraceptive pill (POP) to individuals who wish to commence the POP as their method of contraception. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals aged 13 years and over who wish to commence the POP as their method of contraception and have no absolute or relative contraindications to its use, and where they have been fully counselled about all methods of contraception available to them. **Note:** The healthcare professional must use their professional judgement to consider, and where appropriate, act on any child protection and wellbeing issues coming to their attention as a result of providing the service. This should be in line with local child protection procedures and any national or local guidance on under 16s sexual activity. An individual under 16 years of age may give consent for the supply of the DSG 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 (Scotland) Act 1991, Section 2 (4) (commonly referred to as Fraser guideline) 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'.

	Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical assessment which is normally that of a medical practitioner, then that healthcare professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure or treatment. If under 13 years of age this PGD cannot be used and the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. Prior to the administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy the local and national adult protection procedures followed if appropriate and required. **A child or adult protection concern is not an exclusion criteria for the PGD as the pregnancy risk might continue**.
Exclusion criteria	• Under 13 years (the healthcare professional should speak to the local Child Protection lead and follow the local child protection policy) • 55 years of age and over • Between 13 and 15 years of age and assessed as not competent to consent to treatment using Fraser guidelines • Individuals for whom no valid consent has been received • Pregnancy or suspected pregnancy (if menstrual period is late, there has been a risk of pregnancy or in case of symptoms of pregnancy, pregnancy should be excluded by a urine pregnancy test taken 21 days after the last unprotected sex before POP is supplied) • Allergy or hypersensitivity to POP or any of the medicines excipients (some generic desogestrel products contain soya and/or peanut oil) • Currently using enzyme-inducing drugs or enzyme-inducing herbal products or within 4 weeks of stopping them • Currently on other medication interacting with DSG POP (consider using the BNF interaction checker). • Severe renal insufficiency or acute renal failure **Medical conditions** • Acute porphyria • Current or past history of breast cancer • Benign liver tumour (hepatocellular adenoma) • Malignant liver tumour (hepatocellular carcinoma) • Severe decompensated cirrhosis

	• Current or past history of ischaemic heart disease, stroke or transient ischaemic first attack, if taking a POP when the event occurred. **Special precautions** (DSG POP not contraindicated but might be less effective - advise Long Acting Reversible Contraception (LARC) or, at least, additional condom use): • History of bariatric surgery • Inflammatory bowel disease with malabsorption due to severe small bowel disease or resection, or which causes vomiting or severe diarrhoea for more than 24 hours • Individuals on weight loss medication that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) or with an eating disorder with induced vomiting and/or diarrhoea.
Precautions and special warnings	• Mild/moderate renal insufficiency or treated hypoaldosteronism - monitoring of blood pressure and U+Es may be required (in consultation with individual's renal physician / endocrinologist) • Blood pressure check and U+Es should also be considered prior to supply of desogestrel POP for those with significant risk factors for chronic renal disease e.g. hypertension, cardiovascular disease, diabetes, particularly if age over 50 years. • Any gender based violence, child protection and welfare issues should be referred through the appropriate channels. • Offer LARC to all individuals, but in particular those with medical conditions for whom pregnancy presents an unacceptable risk or 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: intrauterine devices (copper or hormone devices) and subdermal implant. If a LARC method is unacceptable or unsuitable and a POP is chosen then an additional barrier method of contraception is advised. See FSRH advice.
Action if excluded from treatment	Refer to GP or local sexual health service (SHS) for further consultation. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.

Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual declines treatment. Document that the supply was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Progestogen only pill (POP) Desogestrel 75micrograms tablets. **Note:** This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to.
Legal status	Progestogen only pill (POP) Desogestrel 75micrograms tablets is a Prescription-only Medicine (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.
Is the use out with the SmPC?	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. Where a medicine is recommended off-label the individual must be informed prior to the supply that the medicine is being offered in accordance with national guidance but that this is outside the product licence. 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 refer to individual NHS board guidance on storage and handling of medicines guidance.
Dosage/Maximum total dose	• 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 (LNG-EC), additional contraception is required for 48 hours • Treatment should be delayed for 5 days following administration of ulipristal acetate emergency contraception (UPA-EC). Additional contraception for 48 hours should be advised once POP commenced • 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
Frequency of dose/Duration of treatment	Taken orally every day without a pill free break. Can be supplied under PGD for as long as POP contraception is required and the individual meets the PGD inclusion criteria.
Maximum or minimum treatment period	N/A
Route/Method of administration	Oral
Quantity to be supplied	Desogestrel tablets 75micrograms - 3 x 28 tablet pack (3 month supply) per initial supply. Desogestrel tablets 75micrograms - 12 x 28 tablet pack (12 month supply) per repeat supply. Can be supplied under PGD for as long as POP contraception is required and the individual meets the PGD inclusion criteria.
Storage requirements	Desogestrel tablets 75micrograms - Store the blister pack in the original sachet in order to protect from light and moisture.
Follow-up (if applicable)	Return appointment to be made 2 weeks prior to initial POP supply finishing. Review regarding side effects/compliance after first three months. Subsequent reviews should be undertaken at the point of each new supply under the PGD.
Advice (Verbal)	• The advantages and disadvantages of using the POP including the contraceptive effectiveness with both typical use (9% pregnancy risk in the first year of use) and perfect use • About the superior effectiveness of LARC (under 1% pregnancy risk per year of use)

	• Advise individual what to expect and of the possible side effects and their management, including the altered bleeding patterns (unpredictable, irregular) that may occur with the use of POP • How POP contraception works and importance of taking it correctly • When to start taking and when the individual will be protected from pregnancy • Action to take if they forget to take a tablet: Take the next pill as soon as is remembered and carry on with the next pill at the right time. If the pill was more than 12 hours overdue they are not protected, and should consider emergency contraception if unprotected sex has taken place since forgetting the pill. Continue normal pill-taking but must also use another method of contraception, such as the condom, or abstain for the next 2 days (48 hours) • If emergency contraception is required advise LNG-EC as an alternative if an intra-uterine device is not acceptable. Additionally advise that in theory UPA-EC may be less effective if progestogen contraception has been used within the previous 7 days. They should also be advised to delay restarting POP for 5 days after UPA-EC and that additional contraception, e.g. condoms are required for a further 2 days • Advise that risk of any pregnancy is low during proper use of effective contraception. Of pregnancies that occur during use of the traditional POP, 1 in 10 may be ectopic • Medication prescribed and purchased over the counter (including herbal remedies, e.g. St John's Wort) can interfere with the efficacy of the POP • If vomiting occurs within 4 hours of taking a tablet, another should be taken as soon as possible and the missed pill advice followed if appropriate • If attending a GP or other healthcare professional for any illness or a new or change of drug prescription they should make them aware that they are using the POP • If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24 • Individuals should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. **Note:** Where appropriate safer sex should be discussed, advised on STI risk, regular STI screening and condom use encouraged.

Advice and further information	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Further reliable written information or a link to reliable information to support effective use (how to take the pill and what to do if use is incorrect) in an accessible format and language should also be made available to the individual.
Identifying and managing possible adverse reactions	Commonly reported side effect of taking the POP include: • Irregular vaginal bleeding Although commonly reported there is no clear evidence that the following side effects are caused by the POP: • Low mood • Acne • Breast tenderness • Headache • Low sexual desire • Weight gain. This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions. **BNF**: BNF British National Formulary - NICEB **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment if appropriate and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA.
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone

	• Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake supply of the medicine • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD. • Having had training in safeguarding children and vulnerable adults.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD. • Have knowledge and familiarity of the following; o SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

	Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Nurses and midwives working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply/administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GP. 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.
Record of supply	An electronic or paper record must be completed to allow audit of practice. An electronic/HEPMA record of the screening and subsequent supply, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD, it should include as a minimum: • Date and time of supply • Individuals name and CHI • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine, and who undertook the assessment of the individual's clinical suitability for the administration/supply of the medicine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner).

	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 • Individual's GP records if appropriate • HEPMA • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Desogestrel 75microgram film coated tablet (Cerazette®) - Date of revision of text 16/08/22 accessed 27/09/22. British National Formulary https://www.bnf.org/products/bnf-online/ accessed 27/09/2022. Faculty of Sexual and Reproductive Health: Clinical Guideline: Progestogen-only Pills (Amended October 2022). Faculty of Sexual and Reproductive Health: Clinical Guideline: Drug Interactions with Hormonal Contraception (May 2022). Faculty of Sexual and Reproductive Health: CEU Statement: Contraception for Women with Eating Disorders (June 2018, updated May 2021) Faculty of Sexual and Reproductive Health: Clinical Guideline: Combined Hormonal Contraception (November 2020). Faculty of Sexual and Reproductive Healthcare: Clinical Guideline: Overweight, Obesity and Contraception (April 2019) Faculty of Sexual and Reproductive Healthcare: UK Medical Eligibility Criteria for Contraceptive Use (2016 Amended 2019).

	FSRH CEU Statement: Contraception for women using known teratogenic drugs or drugs with potential teratogenic effects (February 2018) Faculty of Sexual and Reproductive Healthcare: Clinical Guideline: Quick Starting Contraception (April 2017) Faculty of Sexual and Reproductive Healthcare: Clinical Guideline: Sexual and Reproductive Health for Individuals with Inflammatory Bowel Disease (October 2016)

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 The Desogestrel Progestogen Only Contraceptive Pill By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

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 The Desogestrel Progestogen Only Contraceptive Pill By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles
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

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**