Patient Group Direction

Supply of Desogestrel Progestogen-Only Contraceptive Pill (POP) by Community Pharmacists Protocol Number 584 Version 1

Date protocol prepared: September 2021

Date protocol due for review: November 2023

Expiry Date: November 2024

This patient group direction must be signed by all health care professionals involved in its use. NHS Forth Valley should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Organisation	NHS Forth Valley

Job Title	Name	Signature	Date
Director of Nursing	Angela Wallace	Signed by Angela Wallace	26/10/21
Medical Director	Andrew Murray	Signed by Andrew Murray	26/10/21
Director of Pharmacy	Scott Mitchell	Signed by Scott Mitchell	26/10/21

This document authorises the supply of **Desogestrel** by appropriate practitioners to patients who meet the criteria for inclusion under the terms of the document.

Practitioners seeking to supply **Desogestrel** must ensure that they assess all clients to make sure they meet the criteria before supplying the product.
The purpose of this Patient Group Direction is to help patients by ensuring that they have ready access to a quality assured service which provides a timely, consistent and appropriate supply of **Desogestrel** for **Contraception.**

National Patient Group Direction (PGD)

Supply of Desogestrel Progestogen-Only Contraceptive Pill (POP) Version – 1.0

This PGD authorises an initial supply of Desogestrel in patients over 13 years and under 55 years of age who meet the criteria for inclusion under the terms of this document, by registered pharmacists delivering the Public Health Service within Community Pharmacies.

Change History - None

PGD desogestrel tablets

Authorisation

This specimen PGD has been produced in collaboration with the Primary Care Community Pharmacy Group and Scottish Lead Clinicians for Sexual and Reproductive Health to assist NHS Boards to provide uniform services under the 'Public Health Service' banner across NHS Scotland. 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 desogestrel tablets 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 marketing authorisation holder's summary of product characteristics (SPC) 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. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

This specimen PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor	Laura Ryan	Signature	Laura Ryan
Pharmacist	John McAnaw	Signature	John McAnaw
NHS Scotland Representative	Jim Miller	Signature	Jim Miller

Approved on behalf of NHS Forth Valley by

Medical Director	Andrew Murray	Signature	Andrew Murray
Director of Pharmacy	Scott Mitchell	Signature	Scott Mitchell
Director of Nursing	Angela Wallace	Signature	Angela Wallace
Date Approved	26/10/21		
Effective from	26/10/21	Review Date	November 2023

Clinical Situation

Indication	The patient wishes to use desogestrel POP as their method of contraception.
Inclusion Criteria	• Patients aged 13 and over who wish to commence desogestrel as an interim measure prior to obtaining their preferred 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. ○ This may be issued at the time of emergency hormonal contraception (EHC) supply or following a consultation regarding the use of contraception. **Note**: If the patient is under 16 years of age local Health Board child protection procedures should be followed. • A patient under 16 years of age may give consent for the supply of desogestrel, provided they understand fully the benefits and risks involved. The patient should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the patient indicates that they wish to accept the supply, supply should proceed, if the pharmacist deems the patient 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. Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical procedure which is normally that of a medical practitioner, then that health care 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. • Patient must be registered with a GP practice in Scotland • Patient has given valid consent to treatment (consent must be in line with local Health Board policy)
Exclusion Criteria	• Under 13 years old (the healthcare professional should speak to the local Child Protection lead and follow the local child protection policy.) • 55 years of age and over • Under 16 years of age and assessed as not competent to consent to treatment under Age of Legal Capacity (Scotland) Act 1991 • Currently using regular hormonal contraception (i.e. missed pill) • Already received the maximum 6 month supply of desogestrel from community pharmacy • Known 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 before desogestrel is supplied. • Has unexplained vaginal bleeding • Has hypersensitivity to the active substance or any of the excipients (some generic desogestrel products contain soya and/or peanut oil) • Has experienced ill health related to previous hormonal contraception use which cannot be attributed to oestrogen • Has an underlying condition which has been exacerbated by previous hormonal contraception use • Has severe liver cirrhosis with abnormal Liver Function Tests (LFTs) or a liver tumour (adenoma or carcinoma) • Has or had a known hormone-dependent malignancy (e.g. breast cancer) • Has known acute porphyria • Currently using enzyme-inducing drugs / herbal products or within 4 weeks of stopping them – check the latest edition of the British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk, FSRH guidance and the HIV Drug Interactions website (www.hiv-druginteractions.org) • Any bariatric or other surgery resulting in malabsorption from the gastrointestinal tract • Patient not registered with a GP practice in Scotland (patient can still seek treatment from local NHS Sexual Health clinic) • No valid consent obtained
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	• Assessed as not competent to consent to treatment • Any child welfare issues should be referred through appropriate channels • Any gender based violence should be referred through appropriate channels • Has uncertainty about the safety of progestogen-only contraception despite counselling • Already used EHC since their last menstrual period • Patient normally uses alternative hormonal contraception, but is not using this form at the point of presentation e.g. run out of pills rather than missed pills, next contraceptive injection/implant has been delayed • Has used ulipristal acetate (UPA-EC) as emergency contraception in the last five days (can be supplied with advice to delay start of desogestrel for five days after taking UPA-EC) • 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 desogestrel is not contraindicated it may be less effective. Advise that Long Acting Reversible Contraception (LARC) is more efficacious. • The patient should be advised that it is possible that medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness of desogestrel. • **Offer advice on Long Acting Reversible Contraception (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: IUD, IUS and implant. If a LARC method is unacceptable/unsuitable and desogestrel is chosen then an additional barrier method of contraception is advised. See FSRH advice** Cautions - see BNF and Summary of Product Characteristics
Action if Excluded	Refer to GP Practice/ Local Sexual health service and document in Patient Medication Record (PMR)
Action if Patient Declines	• Record outcome in PMR • Offer alternative contraceptive advice • Refer to appropriate prescriber for review

Description of Treatment

Name of Medicine	Desogestrel **Note:** This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to.
Strength/Form	75 micrograms tablet
Route of administration	Oral

Dosage	• Single tablet (75 micrograms) taken at the same time each day starting on day 1-5 of the menstrual cycle with no need for additional protection.
	• Desogestrel can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant ("Quick-start"). Additional precautions are then required for 48 hours after starting and if unprotected intercourse has occurred, advise to take follow up pregnancy test at 21 days.
	• Desogestrel can be taken immediately when starting or restarting desogestrel as quick start after levonorgestrel emergency contraception (LNG-EC), additional contraception is required for 48 hours.
	• Treatment with desogestrel should be delayed for 5 days following administration of UPA-EC. Additional contraception for 48 hours should be advised once desogestrel commenced.
	• When changing from combined oral contraceptive: Can be initiated immediately if combined oral contraceptive has been used consistently and correctly or if the healthcare professional is reasonably certain that the individual is not pregnant and that there has been no risk of conception.
	• After pregnancy: up to day 20 no additional contraceptive method required, from day 21 advise additional contraceptive method for first 48 hours.
	• Following termination of pregnancy or miscarriage:
	  o Desogestrel can be initiated on the day of,
	  o Or up to 4 days following surgical termination, of second part of medical termination or miscarriage with no additional contraceptive method required.
	  o Desogestrel started 5 days after event, advise additional contraceptive method for first 48 hours.

Frequency	Once a day at the same each day to be taken continuously without a break between packs.
Duration of treatment	Normally 3 months supply from community pharmacy
Maximum or minimum treatment period	Minimum 3 month to a maximum 6 month treatment period from community pharmacy as per service specification
Quantity to supply/administer	84 tablets (3 x 28) Initially 3 months should be supplied.

	A further 3 months (84 tablets) can be supplied in exceptional circumstances e.g. COVID related restrictions prevent patient accessing continuing supply from GP practice or Sexual Health Services
▼ additional monitoring	No
Legal Category	POM (Prescription Only Medicine)
Is the use outwith the SPC	Yes. It is outside the terms of the product licences of all hormonal contraceptives (HC) for a Healthcare Professional to supply HC without being reasonably sure that the patient is not pregnant. However, the FSRH supports quick start of contraceptive methods as described in their guideline[1]. The patient should be informed of this and use of desogestrel outwith licensed indications should be documented in patient's clinical record. 'Quick start' Healthcare practitioners can be reasonably certain that a patient is not currently pregnant if any **one** or more of the following criteria are met and there are no symptoms or signs of pregnancy: • They have not had unprotected intercourse since the start of their last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease. • They have been correctly and consistently using a reliable method of contraception. (For the purposes of being reasonably certain that a patient is not currently pregnant, barrier methods of contraception can be considered reliable providing that they have been used consistently and correctly for every episode of intercourse.) • They are within the first 5 days of the onset of a normal (natural) menstrual period. • They are less than 21 days postpartum (non-breastfeeding women). • They are fully breastfeeding, amenorrhoeic AND less than 6 months postpartum. • They are within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease. • They have not had intercourse for >21 days AND has a negative high-sensitivity urine pregnancy test (able to detect hCG levels around 20 mIU/ml). In-pharmacy testing not required.

	If a patient wishes to wait to start contraception once pregnancy is excluded they should be advised to do so following a negative pregnancy test no sooner than three weeks following the last episode of UPSI. (Vaginal bleeding following EHC cannot be relied upon as a marker of non-pregnancy). Additional contraception e.g. barrier method should be used for the first 2 days when desogestrel is started outwith the first 5 days of a normal menstrual period. When quick start is offered, the patient should be informed of the potential risks and advised of the need for a pregnancy test 21 days after last unprotected sex. 1. Faculty of Sexual & Reproductive Healthcare. *FSRH Guideline Quick Starting Contraception*. 2017. London. Available at FSRH Clinical Guideline: Quick Starting Contraception (April 2017) - Faculty of Sexual and Reproductive Healthcare (Accessed 03/06/2021)
Storage requirements	As per manufacturer's instructions
Additional information	None

Warnings including possible adverse reactions and management of these	Commonly reported side effects of taking desogestrel include: • Irregular bleeding, amenorrhoea • Nausea and vomiting • Breast tenderness • Dizziness, headache and depression • Changes in body weight and libido. **This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.** BNF: https://www.bnf.org/products/bnf-online/ SmPC: https://www.medicines.org.uk/emc/ • The patient must be advised to contact the place of issue or other appropriate practitioner (e.g. their own GP practice or local Sexual Health Service if available): o if they are concerned about any changes in their health that they feel may be due to desogestrel. o if they are concerned about any circumstance that may affect the efficacy of desogestrel. o to report any adverse reactions as soon as possible
Reporting procedure for adverse reactions	• Pharmacists should document and report all adverse incidents (actual and suspected) through their own internal governance systems and notify the appropriate medical practitioner for documenting in the patient's medical record as appropriate. • Where appropriate, use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/
Advice to Patient/carer including written information	Verbal Advice • The mode of action, efficacy and failure rate of the treatment • Advantages and disadvantages of using desogestrel • How to take the medication - Treatment to commence immediately after LNG-EC or 5 days after UPA-EC • Possible side effects • Expected bleeding pattern • The need, length and method of extra precautions (if required) • The need and timing of a pregnancy test (if required with 'Quick starting') • How to deal with a 'missed dose' : 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. Continue normal pill-taking but must also use another method of contraception, such as the condom, for the next 2 days • When and where to access emergency contraception (if required) • Medication: prescription and non-prescription (including herbal remedies, e.g. St John's Wort) can interfere with the efficacy of desogestrel. • Advise that it is possible that medications that induce diarrhoea and/or vomiting (e.g. laxatives) could reduce the effectiveness of desogestrel • If vomiting occurs within 2 hours of taking a tablet, another should be taken as soon as possible and the missed pill advice (included in PIL) followed if appropriate • Details of follow up – confirm patient is happy for pharmacist to make GP aware of this supply and advise that patient should contact local GP practice or Sexual Health Service before the three month supply runs out to arrange supply of future contraception (ideally this should happen as soon as possible). • If attending a GP or other healthcare professional for any illness they should make them aware that they are using desogestrel. • Sexually transmitted infections – advise on STI risk, regular STI screening and condom use encouraged. <u>Written Advice or directed to relevant online information</u> • Details of local Sexual and Reproductive Services and how to contact them • The Drug Manufacturer Patient Information Leaflet should be given. Patients should be informed who to contact should they experience an adverse drug reaction • Direct patient to NHS Inform for information on alternative forms of contraception (print out for patient if required): The different types of contraception | NHS inform • Display QR code with link to NHS Inform on wall of consultation room
Monitoring	Not required in Community Pharmacy
Follow-up	Not required in Community Pharmacy
Additional Facilities	The following should be available where the medication is supplied: • A private area where a consultation can be conducted without being overheard to respect the patient's right to confidentiality and safety • 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 • Access to current BNF (online version preferred)

Characteristics of staff authorised under the PGD

Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration.
Specialist competencies or qualifications	Has undertaken appropriate training to carry out clinical assessment of patient according to the indications listed in this PGD, by successfully completing NES Pharmacy e-learning module on "Bridging Contraception". https://learn.nes.nhs.scot/49300/pharmacy/cpd-resources/sexual-health-for-community-pharmacy-bridging-contraception-bc Able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent. Due to the minimum age of potential patients, pharmacists must be familiar with local and national child protection guidelines and local contacts to report information if required. Must be familiar with the desogestrel SPC. Authorised to use PGD on completion and submission of an approved practitioner form. ***Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD.***
Continuing education and training	It is the responsibility of the individual to keep up-to-date with continued professional development. Has read the most up to date guidance on POP FSRH clinical guidance: Progestogen-only Pills – Clinical Effectiveness unit. March 2015 (Amended April 2019). Available at: fsrh-guideline-progestogen-only-pills-april-2019.pdf (Accessed 06 May 2021) FSRH guideline: Quick starting contraception Available at: 1fsrh-guideline-quick-starting-contraception-april-2017 (4).pdf (Accessed 06 May 2021) National Institute for Health and Care Excellence (NICE). Contraception – progestogen-only methods. Available at Contraception - progestogen-only methods | Health topics A to Z | CKS | NICE (Accessed 06 May 2021) Attends approved training and training updates as appropriate. Undertakes CPD when PGD or NES Pharmacy module are updated.

Audit Trail

Record/Audit Trail	All records must be clear, legible and in an easily retrieval format. Pharmacists must record in PMR. The following records should be kept (paper or computer based) and are included in the patient assessment form: • Patient's name/parent/guardian/person with parental responsibility, address, date of birth and consent given • Patient's CHI number • Contact details of GP (if registered) • Presenting request for treatment • Details of medicine supplied (including batch number and expiry date) • The signature and printed name of the healthcare professional who supplied the medicine. • Advice given to patient (including side effects) • Whether the patient met the inclusion criteria and whether the exclusion criteria were assessed • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record • Referral arrangements (including self-care) ***The patient's GP, where known, should be provided with a copy of the client assessment form for the supply of desogestrel on the same, or next available working day (valid consent required from patient).*** ***If the patient suffers an adverse drug reaction to desogestrel, the GP should also be informed.*** These records should be retained in accordance with national guidance[2] (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead. All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data. 2. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf (Accessed on 21/05/2021)
Additional references	British National Formulary (BNF) current edition desogestrel SPC.

PATIENT GROUP DIRECTION FOR THE SUPPLY OF DESOGESTREL BY COMMUNITY PHARMACISTS UNDER THE NHS COMMUNITY PHARMACY PUBLIC HEALTH SERVICE

Individual Authorisation

PGD does not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals.

Note to Authorising Authority: authorised staff should be provided with access to the clinical content of the PGD and a copy of the document showing their authorisation.

I have read and understood the Patient Group Direction authorised by each of the individual NHS Boards that I wish to operate in and agree to provide desogestrel tablets.

Name of Pharmacist _____

GPhC Registration Number _____

Normal Pharmacy Location

(Only one Pharmacy name and contractor code is required for each Health Board (HB) area where appropriate. If you work in more than 3 HB areas please use additional forms.)

Name & Contractor code HB (1) _____

Name & Contractor code HB (2) _____

Name & Contractor code HB (3) _____

Please indicate your position within the pharmacy by ticking one of the following:

Locum ☐ Employee ☐ Manager ☐ Owner ☐

Signature _____ Date _____

Please tick and send to each Health Board you work in. Fax numbers, email and postal addresses are given overleaf.

Ayrshire & Arran	☐	Grampian	☐	Orkney	☐
Borders	☐	Gr Glasgow & Clyde	☐	Shetland	☐
Dumfries & Galloway	☐	Highland	☐	Tayside	☐
Fife	☐	Lanarkshire	☐	Western Isles	☐
Forth Valley	☐	Lothian	☐		

NHS Board	Address	Fax Number
Ayrshire & Arran	Iain Fulton, NHS Ayrshire & Arran, Eglington House, Ailsa Hospital, Dalmellington Road, Ayr, KA6 6AB margaret.scott3@aapct.scot.nhs.uk	Please e-mail or post
Borders	Adrian Mackenzie, Lead Pharmacist Pharmacy Department, Borders General Hospital, Melrose, TD6 9BS communitypharmacy.team@borders.scot.nhs.uk	Please e-mail or post
Dumfries & Galloway	NHS Dumfries & Galloway, Primary Care Development, Ground Floor North, Mountainhall Treatment Centre, Bankend Rd, Dumfries, DG1 4TG Dg.pcd@nhs.scot	Please e-mail or post
Fife	PGD Administrator, Pharmacy Services, NHS Fife, Pentland House, Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW Fife.pgd@nhs.scot	Please e-mail or post
Forth Valley	Community Pharmacy Development Team, Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR fv.communitypharmacysupport@nhs.scot	Please e-mail or post
Grampian	Pharmaceutical Care Services Team NHS Grampian, Pharmacy & Medicines Directorate, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS gram.pharmaceuticalcareservices@nhs.scot	Please e-mail or post
Greater Glasgow & Clyde	Janine Glen, Contracts Manager, Community Pharmacy, NHS Greater Glasgow & Clyde, Clarkston Court, 56 Busby Road, Glasgow G76 7AT ggc.cpdevteam@nhs.scot	0141 201 6044 Or e-mail
Highland	Community Pharmaceutical Services, NHS Highland, Assynt House, Beechwood Park, Inverness. IV2 3BW nhsh.cpsoffice@nhs.scot	Please e-mail or post
Lanarkshire	Pharmacy/Prescribing Admin Team, NHS Lanarkshire Headquarters, Kirklands, Fallside Road, Bothwell, G71 8BB PharmacyAdminTeam@lanarkshire.scot.nhs.uk	Please e-mail or post
Lothian	Primary Care Contractor Organisation, 2ND Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG CommunityPharmacy.Contract@nhslothian.scot.nhs.uk	Please e-mail or post
Orkney	Lyndsay Steel, Lead General Practice Pharmacist. The Balfour, Foreland Road, Kirkwall, KW15 1NZ Phone: 01856 888 911 ork.primarycarepharmacy@nhs.scot	Please e-mail or post
Shetland	Mary McFarlane, Principle Pharmacist, NHS Shetland, Gilbert Bain Hospital, Lerwick, Shetland, ZE1 0TB	01595 743356
Tayside	Diane Robertson, Pharmacy Department, East Day Home, Kings Cross Hospital, Clepington Road, Dundee, DD3 8AE Diane.Robertson9@nhs.scot	Please e-mail or post
Western Isles	Michelle Taylor, Primary Care Department, The Health Centre, Springfield Road, Stornoway, Isle of Lewis, HS1 2PS	No fax, please post