NHS Circular:
PCA (P)(2021) 12

Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

23 September 2021

Addresses

For action

Chief Executives, NHS Boards
Directors of Pharmacy
Director of Practitioner Service, NHS NSS

For information

Chief Executive, NHS NSS

Enquiries to:

Pharmacy Team
1st Floor East Rear
St Andrew's House
EDINBURGH
EH1 3DG

Email:
PharmacyTeam@gov.scot

www.gov.scot

Dear Colleague

ADDITIONAL PHARMACEUTICAL SERVICES PUBLIC HEALTH SERVICE – ADDITION OF BRIDGING CONTRACEPTION

Purpose

1. This Circular advises that supply of bridging contraception will be added to the community pharmacy Public Health Service from 9 November 2021.

Background

2. NHS Circular PCA (P)(2015) 20 issued on 14 September 2015, enclosed updated Directions for the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2015 which came into force on 1 October 2015, alongside an updated service specification for the supply of Emergency Hormonal Contraception (EHC).

Detail

3. The Directions for the Public Health Service are amended by the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Amendment Directions 2021 ("the Amendment Directions") to enable community pharmacies to provide a 3 month supply of desogestrel as bridging contraception. The Amendment Directions come into force on 9 November 2021.

4. A supply may be made following on from an Emergency Hormonal Contraception (EHC) consultation, or where no EHC is required a supply can be made as a standalone temporary supply of contraception when an individual requests this. This is intended to support access to contraception. The service follows on from the successful Bridge-IT pilot undertaken in a number of community pharmacies.

5. The Amendment Directions are attached to this Circular as **Annex A**.

6. Community pharmacy contractors and pharmacy teams should ensure they are familiar with the new arrangements as detailed below.

Service Specification for Bridging Contraception and Directions

7. A service specification for bridging contraception is attached to this circular as **Annex B**. This service specification should be read alongside the PGD.

Patient Group Direction (PGD)

8. A national PGD has been developed for the Public Health Service for the supply of desogestrel.

9. **Annex C** of this circular provides a copy of the draft PGD which has been approved by NHS24. Health Boards will approve and publish this PGD in due course. Individual authorisation forms should be completed by Pharmacists delivering the Public Health Service and submitted to each Health Board area that they work in according to the usual process.

Training

10. Community pharmacy contractors should ensure that their pharmacists complete the e-learning module for bridging contraception, now available on the NES TURAS Learn website at: https://learn.nes.nhs.scot/49300/pharmacy/cpd-resources/sexual-health-for-community-pharmacy-bridging-contraception-bc In addition, a webinar to support the implementation of the service will be held on Monday 4th October at 19:00. Details of how to register can be found at: https://learn.nes.nhs.scot/57725/pharmacy/pharmacy-courses-and-events/webinar-bridging-contraception

11. NHS Circular PCA (P)(2021) 5 issued on 8 April 2021, advised that the 2021/22 Quality Improvement payment supports the implementation and training requirements for the Public Health Service - Bridging Contraception.

IT roll-out

12. All Patient Medication Record (PMR) suppliers have confirmed that pharmacy IT software will support pharmacy teams to deliver bridging contraception from the launch date of 9 November 2021.

Remuneration arrangements

13. NHS Circular PCA (P)(2021) 5 issued on 8 April 2021, set out the remuneration arrangements for bridging contraception. A remuneration funding pool will provide a payment to contractors of £30 per bridging contraception consultation undertaken. Payment verification and counter-fraud checks will be determined as appropriate by National Services Scotland (NSS).

14. Community Pharmacy Scotland has been consulted on the contents of this Circular and the Scottish Drug Tariff is being amended.

Actions

Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists, GPs, Health and Social Care Partnerships and Area Pharmaceutical Committees.

Health Boards are asked to ensure that community pharmacy contractors have contact details for local sexual health services.

Yours sincerely

Alison Strath
Chief Pharmaceutical Officer

ANNEX A

NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (PUBLIC HEALTH SERVICE) (SCOTLAND) AMENDMENT DIRECTIONS 2021

The Scottish Ministers give the following Directions in exercise of the powers conferred by sections 2(5), 27A, 27B, 28A and 105(7) of the National Health Service (Scotland) Act 1978[1], and all other powers enabling them to do so.

Citation and commencement

1. These Directions may be cited as the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Amendment Directions 2021 and come into force on 9 November 2021.

Amendment of the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2015

2. The Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2015[2] are amended in accordance with paragraphs 3 to 5.

3. In paragraph 3.1, after "(EHC)" insert ", bridging contraception".

4. In Schedule 1—
   (a) in paragraph 1(f), after "(EHC)" insert ", bridging contraception"; and
   (b) in paragraph 2, after "(EHC)" insert "or bridging contraception".

5. In paragraph 1 of Schedule 2 —
   (a) after sub-paragraph (a) insert "(aa) the patient's date of birth;", and
   (b) after sub-paragraph (b) insert "(ba) the patient's sex;".

Signed by Alison Strath
A member of staff of the Scottish Ministers

St Andrew's House,
Edinburgh
22 September 2021

[1] 1978 c.29; section 2(5) was amended by the National Health Service and Community Care Act 1990 (c.19), section 66(1) and schedule 9; section 27A was inserted by the National Health Service (Primary Care) Act 1997 (c.46) ("the 1997 Act"), section 27(2); section 27B was inserted by the 1997 Act, section 28(2); section 28A was inserted by the Health Act 1999 (c.8) ("the 1999 Act"), section 57(1), section 105(7) was amended by the Health Services Act 1980 (c.53), schedules 6 and 7, the Health and Social Services and Social Security Adjudications Act 1983 (c.41), section 29(1) and schedule 9, and the 1999 Act, schedule 4. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).
[2] Attached to PCA (P) (2015) 20. www.sehd.scot.nhs.uk/pca/PCA2015(P)20.pdf

ANNEX B

BRIDGING CONTRACEPTION SERVICE SPECIFICATION

PROVISION OF DESOGESTREL

1. Background

1.1 The community pharmacy sexual health service is part of the Public Health Service element of the community pharmacy contract.

1.2 The Directions for the Public Health Service have been amended to add bridging contraception.

1.3 This service specification should be read in conjunction with the Patient Group Direction (PGD) for the supply of desogestrel and the Directions for the Public Health Service.

2. Service aim

2.1 To increase access to contraception and aim to reduce the incidence of unplanned pregnancy.

2.2 To provide the client with 'bridging contraception' which is a short term supply, giving the client time to access their GP or sexual health services for a longer term supply of contraception.

3. Service outline and standards

3.1 The service is available to any client aged over 13 years and under 55 years at risk of pregnancy. The person must also be registered with a GP practice in Scotland.

3.2 The service must be provided by the pharmacist.

3.3 Using the PGD and proforma questionnaire, the pharmacist takes a client history to ensure that they have sufficient information to assess the appropriateness of the supply.

3.4 The supply of desogestrel is to be provided either:

- at the same time as a supply of Emergency Hormonal Contraception (EHC), or
- where the client has requested a short term supply of desogestrel.

3.5 The pharmacist supplies desogestrel where clinically indicated, recording the supply using the electronic claim framework and following the procedure set out in section 4 below.

3.6 In accordance with the national PGD, the pharmacist can supply:

- a 3 month supply of desogestrel 75 microgram Film-coated Tablets, 84 tablets (3 x 28)

3.7 The Pharmacist is responsible for ensuring that the service is welcoming, user-friendly, non-judgemental, person-centred and confidential.

3.8 A pharmacist who chooses not to supply desogestrel on the grounds of religious, moral or ethical reasons must treat the matter sensitively and they are required to advise the client on an alternative local source of supply (for example another pharmacy, GP practice or sexual health service).

3.9 The service should be operated from premises that can provide an acceptable level of privacy to respect a client's right to confidentiality and safety.

3.10 The pharmacist must use their professional judgement to consider, and where appropriate, act on any child protection 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 (e.g. Fraser Guidelines).

3.11 The service is primarily intended to comprise a face-to-face consultation, however, the pharmacist may consider whether it would be appropriate to conduct a consultation by telephone call or using NHS Near Me, particularly in situations where a client is shielding or self-isolating.

3.12 The pharmacist must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. Wherever possible, clients should be identified using a CHI number.

3.13 The pharmacist must ensure, where appropriate, that the client is signposted to other sexual and reproductive health matters and related topics, including the promotion of long-acting contraception and the prevention and screening of sexually transmitted infections. Written information may be available on these topics from the health board or the client can be referred to the NHS Inform website. A QR code for the relevant NHS Inform section can be scanned by smartphones.

3.14 The service should be provided according to any required regulatory and professional standards.

4. Service Procedure

4.1 The pharmacist follows the procedure detailed below:

a) Supply following an EHC consultation

- Following on directly from an EHC consultation, the pharmacist informs the client of the availability of bridging contraception and, using the PGD and desogestrel proforma questionnaire, establishes whether a 3 month supply of desogestrel would be appropriate. This consultation should use the client history taken during the EHC consultation and consider any contra-indications, previous use and current medication to ensure the supply is safe and appropriate.

- The client is counselled on the use of desogestrel and advised at what point following EHC the desogestrel should be taken. This will vary depending whether the EHC supply is levonorgestrel or ulipristal acetate. Refer to the PGD on desogestrel for dosing instructions.

b) Standalone supply

- Where a client requests a supply of contraception, the pharmacist informs the client of the availability of bridging contraception and undertakes a desogestrel consultation, using the PGD and desogestrel proforma questionnaire, to establish whether a 3 month supply of desogestrel would be appropriate. This consultation should take the client's details and consider any contra-indications, previous use and current medication to ensure the supply is safe and appropriate.

In the cases of both a) and b):-

- The supply is made and recorded in the patient medication record.

- The 'Quick Starting' approach may be followed. This is when the client can start taking desogestrel straight away without waiting until the first day of their next period. Further information on 'quick starting' is within the PGD and training module.

- With the client's consent, the client's GP practice is notified of the supply of desogestrel in line with the PGD. The client should be assured that this is usual practice and assists with continuity of supplies and ensuring medical records are updated.

- The supply is intended as a one–off 3-month supply, however, where a client has been unable to secure an ongoing supply in that time period, the pharmacist may provide **one** further 3-month supply.

- If the pharmacy already offers free condoms via health board C-card arrangements this should be offered at the same time as desogestrel.

- The pharmacist counsels the client on the importance of using regular contraception if they are sexually active, the advantages of long acting reversible contraception, and promotes the role of condoms in preventing sexually transmitted infections.

- The pharmacist provides the client with written advice or referral to NHS Inform online guide to contraception. A QR code to direct clients to NHS Inform is provided below. Printing out information if necessary, the pharmacist provides any additional written and verbal advice on the risk of sexually transmitted infections as a result of unprotected sex and future contraceptive needs. The pharmacist also provides information on local services or agencies who can provide access to further treatment and services if required.

- Any suspected adverse events should be reported using the MHRA Yellow Card Scheme.

5. Training

5.1 This service specification must be read alongside the bridging contraception PGD.

5.2 Training resources are available on NES Turas Learn including the e-learning module 'Sexual Health for Community Pharmacists : Bridging Contraception (desogestrel)'

https://learn.nes.nhs.scot/49300/pharmacy/cpd-resources/sexual-health-for-community-pharmacy-bridging-contraception-DESOGESTREL

6. Remuneration and Reimbursement

6.1 The pharmacist uses the Universal Claim Framework (UCF) to claim for the service(s) they have provided i.e:-

- EHC only
- BRIDGING CONTRACEPTION only
- EHC + BRIDGING CONTRACEPTION

6.2 A claim for bridging contraception can be made when a bridging contraception consultation has been fully undertaken, regardless of whether this consultation has resulted in supply, referral of the client to another service provider, or no further action.

6.3 Details of remuneration fees and reimbursement are set out in the Scottish Drug Tariff.

NHS Inform – Guide to Contraception – QR Code

QR Code for web page https://www.nhsinform.scot/healthy-living/contraception

ANNEX C

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

Doctor	_____	Signature	_____
Pharmacist	_____	Signature	_____
Nurse	_____	Signature	_____

Approved on behalf of NHS [insert details] by

Medical Director	_____	Signature	_____
Director of Pharmacy/Senior Pharmacist	_____	Signature	_____
Clinical Governance Lead	_____	Signature	_____

Date Approved _____

Effective from _____ Review Date _____

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:
	  ○ Desogestrel can be initiated on the day of,
	  ○ Or up to 4 days following surgical termination, of second part of medical termination or miscarriage with no additional contraceptive method required.
	  ○ 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): ○ if they are concerned about any changes in their health that they feel may be due to desogestrel. ○ if they are concerned about any circumstance that may affect the efficacy of desogestrel. ○ 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): <u>The different types of contraception | NHS inform</u> • 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

Forms to follow from individual Health Boards once PGD is signed off locally.

Patient Group Direction for the provision of desogestrel progestogen-only pill (POP) for the purposes of Bridging Contraception to patients aged over 13 years and under 55 years from Community Pharmacy

Patient assessment form

Patient Name:	Click or tap here to enter text.	**Date of Birth /CHI:**	Click or tap here to enter text.
Patient Address (including postcode):	Click or tap here to enter text.	**GP name and practice address:**	Click or tap here to enter text.
Date of assessment:	Click or tap to enter a date.	**Patient consents to GP being informed:**	Yes ☐ No ☐

Is patient aged between 13 and 55 years and competent to consent?	YES	☐	**Proceed with consultation**
	NO	☐	Under 13 years / Child protection issues: **Follow local Health Board Child Protection Policies** Not competent to consent: **Refer to appropriate practitioner**
Is patient registered with a GP practice in Scotland	YES	☐	**Proceed with consultation**
	NO	☐	**Refer to appropriate practitioner to obtain supply** (e.g. local Sexual Health Services)
Has patient also received EHC from you today?	YES	EHC plus bridging contraception	☐
	NO	Bridging contraception only	☐

BRIDGING CONTRACEPTION

Patient clinical picture and related appropriate actions

CRITERIA FOR EXCLUSION (Proceed if all 'NO')	Yes	No	Actions
Known or possible 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. However, if you have provided patient with EHC today for a very recent pregnancy risk, patient remains eligible for desogestrel supply using this PGD unless there are other exclusions.	☐	☐	If YES, do not treat and refer
Patient already received maximum 6 month supply of desogestrel from community pharmacy?	☐	☐	If YES, do not treat and refer
Patient currently using regular hormonal contraception?	☐	☐	If YES, do not treat and refer However, if next contraceptive injection is overdue or patient has run out of tablets, supply of desogestrel may be appropriate.
Unexplained vaginal bleeding?	☐	☐	If YES, do not treat and refer
Has hypersensitivity to the active substance or any of the excipients (some generic desogestrel products contain soya and/or peanut oil)?	☐	☐	If YES, do not treat and refer
Has experienced ill health related to previous hormonal contraception which cannot be attributed to oestrogen?	☐	☐	If YES, do not treat and refer
Has an underlying health condition which has been exacerbated by previous hormonal contraception use?	☐	☐	If YES, do not treat and refer
Has severe liver cirrhosis with abnormal LFTs or a liver tumour (adenoma or carcinoma)?	☐	☐	If YES, do not treat and refer
Has or had a known hormone dependent malignancy e.g. breast cancer?	☐	☐	If YES, do not treat and refer

CRITERIA FOR EXCLUSION (Proceed if all 'NO')	Yes	No	Actions
Has known acute porphyria?	☐	☐	If YES, do not treat and refer
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)?	☐	☐	If YES, do not treat and refer
Any bariatric or other surgery resulting in malabsorption from the gastrointestinal tract?	☐	☐	If YES, do not treat and refer

SUITABILITY OF DESOGESTREL?	Yes	No	Actions
Discuss all options for contraception e.g. condoms, POP, COC, LARC (implant, IUD, injection)	☐	☐	
Discuss the benefits of desogestrel – reduced risk of pregnancy, reduces number of appointments needed to commence effective contraception	☐	☐	
Discuss the possible adverse effects of desogestrel • Change of bleeding patterns (irregular/amenorrhoea) • Nausea and vomiting • Breast tenderness • Dizziness, headache, depression • Changes in body weight and libido	☐	☐	
Date on which last menstrual period started			Click or tap to enter a date.
Is supply of desogestrel being introduced by 'quick starting'?	☐	☐	If YES, inform patient that this is not within the SPC for desogestrel
Gain informed consent to treatment with desogestrel from patient	☐	☐	If NO, do not treat and refer

Preparation options and supply method

Medicine and strength	Regimen	Supply method
Desogestrel 75 microgram tablets	One tablet to be taken daily (at the same time each day) to be continued without a break between packs (3 x 28 tablets)	PGD via Sexual Health Service

Patient advice checklist

Advice	Provided (tick as appropriate)
Mode of action discussed? • Primarily works by inhibiting ovulation • Also can increase viscosity of cervical mucus	☐
Efficacy and failure rate discussed? • If used consistently and correctly – over 99% effective • Desogestrel inhibits ovulation in 97% cycles	☐
When to take medication discussed? • Take at same time each day • If > 12 hours late (>36 hours since last pill) – classed as missed pill	☐
Missed pills and emergency contraception discussed? • Take one pill as soon as remembered • Take next pill at normal time (may mean 2 pills taken in 1 day) • Use additional precautions for 48 hours after restarting • EHC required if UPSI occurred after missed pill and within 48 hours of restarting desogestrel	☐
Possible interactions discussed e.g. prescription medication, herbal remedies, laxatives?	☐
Sick day rules • Efficacy of desogestrel may be reduced if suffering from severe vomiting and/or diarrhoea • If vomiting occurs within 2 hours of taking pill, take another pill as soon as possible • If subsequent pill is missed, use additional precautions for 48 hours after resuming pill taking	☐
Extra precautions and pregnancy test (if required) discussed? • Additional contraception required for 2 days if desogestrel started out with first 5 days of natural menstrual cycle ('Quick starting') • When 'quick starting', pregnancy test should be performed not less than 3 weeks after last UPSI • Following use of UPA-EC, patient should wait for 5 days before starting desogestrel and use additional contraception for the first 2 days	☐

Follow up discussed? • 3 month supply – patient to arrange contact with GP practice /Sexual Health Services as soon as possible for continuing contraception	☐
Sexually transmitted infections discussed and how to access screening if appropriate? • Reminder that desogestrel does not protect from STIs • Advice on how to access condoms in local area	☐
Written patient information issued or patient directed to online information? • Desogestrel patient information leaflet issued • Issue 'fpa' Family Planning Association leaflet 'Your guide to the progestogen only pill" (if available) • Direct to NHS Inform (via QR code if appropriate)	☐
PHARMACIST INFORMATION ONLY Has the patient said anything during the consultation which gives you concern about the possibility of non-consensual sex? • Consider local Child Protection procedures • Signpost to relevant support networks e.g. Gender based violence teams in local Health Board	☐

Communication

Contact made with: (if patient consent obtained)	Details (include time and method of communication)
Patient's regular General Practice (details)	Click or tap here to enter text.
Other e.g. local Sexual Health Service	Click or tap here to enter text.

Details of medication supplied and pharmacist supplying under the PGD

Medication supplied	Click or tap here to enter text.			
	First 3 month supply	☐	Second 3 month supply	☐
Batch number and expiry	Click or tap here to enter text.			
Print name of pharmacist	Click or tap here to enter text.			
Signature of pharmacist	Click or tap here to enter text.			
GPhC registration number	Click or tap here to enter text.			

Patient Group Direction for the provision of desogestrel progestogen-only pill (POP) for the purposes of Bridging Contraception to patients aged over 13 years and under 55 years from Community Pharmacy

Notification of supply from community pharmacy

CONFIDENTIAL WHEN COMPLETED

Data protection confidentiality note: this message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

GP name	Click or tap here to enter text.	Pharmacy Stamp
GP practice address	Click or tap here to enter text. Click or tap here to enter text.	
The following patient has attended this pharmacy for assessment and potential supply of desogestrel POP:		
Patient name	Click or tap here to enter text.	
Date of birth/CHI	Click or tap here to enter text.	Pharmacist name Click or tap here to enter text.
Patient address	Click or tap here to enter text. Click or tap here to enter text.	GPhC number Click or tap here to enter text.
Postcode	Click or tap here to enter text.	Date Click or tap to enter a date.

Following assessment (Tick as appropriate)

Your patient has been given a 3 month supply of desogestrel (initial supply)	☐
Your patient has been given a second 3 month supply of desogestrel	☐
Your patient has been given appropriate guidance on use of this medication e.g. side effects, missed pill information	☐
Your patient is unsuitable for treatment via PGD for the following reasons and has been referred: Click or tap here to enter text.	☐

*****Your patient has been advised to contact the practice for subsequent supplies of contraception.*****

You may wish to include this information in your patient records.

Patient consent: I can confirm that the information is a true reflection of my individual circumstances and I give my consent to allow a pharmacist working under the terms of Public Health Service to provide the most appropriate advice and/or treatment for me. I also give my permission to allow the pharmacist to pass, to my own GP, details of this consultation and any advice given or treatment provided. I have been advised that some of the information may be used to assess the uptake of the service but this will be totally anonymous and not be attributable to me.

Patient signature	Date
Click or tap to enter a date.	Click or tap to enter a date.

This form should now be sent to the patient's GP and a copy retained in the pharmacy