Patient Group Direction

For the supply of

Desogestrel 75 microgram Progestogen Only Contraceptive Pill (POP)

By pharmacists providing the NHS Wales Clinical Community Pharmacy Service for

Bridging and QuickStart Oral Contraception

In

Operational from: 21st November 2022

Review Date: 21st October 2025

Version number: v1.0

PGD for the supply of desogestrel 75 microgram Progestogen-Only Contraceptive Pill (POP) by pharmacists delivering the Community Pharmacy Bridging and QuickStart Contraception component of the clinical community pharmacy service

Reference:	Desogestrel 75 microgram tablet PGD
Version no:	01:00
Valid from:	21st November 2022
Review date:	21st October 2025
Expiry date:	20th November 2025

Welsh Medicines Advice Service has developed this PGD for local authorisation

Those using this PGD must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history

Version number	Change details	Date
01.00	Original PGD template developed	1st September 2022

[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178 and 2015 No.323).

1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Reference Group in accordance with the PGD Policy.

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

Expert panel

Name	Designation
Expert Reviewer – Caroline Scherf	Consultant in Sexual and Reproductive Health Cardiff and Vale UHB
Main author - Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Information Centre Cardiff and Vale UHB
Professional group reviewer - Adam Mackridge	Chair of Community Pharmacy Clinical Reference Group and Strategic Lead Pharmacist for Community Pharmacy Betsi Cadwallader UHB

Date CPCRG approval of PGD: 7th November 2022

2. Organisational authorisations

The PGD is not legally valid until it has had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board, to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of the PGD.

authorises this PGD for use by community pharmacies within its area that have been commissioned to provide the Bridging and Quick Start contraception component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGD.

Local Health Board approval (legal requirement) as per health board policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to welshmedicines.information@wales.nhs.uk

Appendix B provides a practitioner listing sheet. Individual practitioners must be listed by name to work to this PGD. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of this PGD.

3. Characteristics of Staff

Qualifications and professional registration	**Practitioners must only work under this PGD where they are competent to do so.** This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC)
Additional requirements	Pharmacists must: ➢ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Community Pharmacy Bridging and QuickStart Oral Contraceptive service. ➢ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing. Appendix B ➢ be familiar with the medicine and alert to changes in the Summary of Product Characteristics (SmPC), ➢ have access to the Patient Group Direction and associated resources (including the service specification and the clinical guidance document supporting the PGD) and must be competent in the use of PGDs. (see NICE Competency framework for health professionals using PGDs). ➢ be named in the All Wales Pharmacy Database for the Bridging and QuickStart Oral Contraceptive service. ➢ have met the training requirements for the service as set out by HEIW (Health Education and Improvement Wales).
Initial training	Pharmacists must: ➢ have completed the HEIW Pharmacy Generic Skills and Competency assessment in line with the National Clinical Services Accreditation Process. ➢ have completed the HEIW Pharmacy Clinical Knowledge Assessment for Bridging Oral Contraception. ➢ be familiar with the British National Formulary (BNF) and SmPC entries for desogestrel. ➢ have awareness of the adverse drug reactions associated with desogestrel. **The pharmacist must be listed by name, under the current version of this PGD that has been issued by the Local health Board in which area they are operating before working under its authority**
Ongoing training and competency	Pharmacists must ➢ undertake regular CPD and maintain own level of competence. and knowledge in this clinical area to provide the service. ➢ be aware of any updates made to the products in SmPC, BNF ➢ be aware of any updates to relevant national and local guidelines. ➢ As registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained in the individual's personal file.

4. Clinical condition

Clinical condition or situation to which this PGD applies	For individuals at risk of pregnancy presenting at the pharmacy who want to use desogestrel Progesterone Only Pill (POP) as an interim measure prior to obtaining their preferred method of contraception (bridging).
Criteria for inclusion	Desogestrel 75 microgram tablets can be given to any individual of childbearing potential including adolescents aged 13 to 54 years, presenting to the community pharmacy who: ➢ Want to use desogestrel contraception as an interim measure prior to obtaining their preferred method of contraception from their GP or sexual health service; **AND** ➢ Have no contraindications to desogestrel ➢ Have given informed consent. ➢ Have been counselled about all methods of contraception available to them. ➢ Are resident in Wales or registered with a GP practice.
Criteria for exclusion[2]	Desogestrel 75 microgram tablets should not be given to individuals: ➢ Where informed consent has not been given. Individuals do not agree to share relevant clinical information or there is no valid consent. ➢ who are aged 12 years and under, follow local safeguarding policy see “action to be taken if patient excluded” ➢ who are under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. ➢ who are 16 years of age and over who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment and lacks capacity to consent. ➢ who are 55 years of age or over. ➢ who are not at risk of pregnancy or not of child bearing potential. ➢ who have a 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. ➢ if they have a known hypersensitivity to desogestrel or any excipients – see SmPC some generic desogestrel products contain soya and or peanut oil. ➢ If they have already received the maximum 6-month supply of desogestrel from community pharmacy.

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Criteria for exclusion continued[2]	➢ Have a history of severe hepatic disease with abnormal liver function tests (LFTs), cirrhosis associated with jaundice, ascites, encephalopathy or gastrointestinal haemorrhage and liver adenoma or carcinoma. ➢ Has an underlying condition which has been exacerbated by previous hormonal contraception use. ➢ Have a current and previous history of sex-steroid sensitive malignancy e.g. breast cancer. ➢ The request is made by a third party on behalf of patient. ➢ Have known acute porphyria. ➢ They have rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. ➢ They are taking enzyme-inducing drugs or herbal products or within 28 days of stopping them. Consult the individual product SmPC, the BNF, the Faculty of Sexual and Reproductive Health (FSRH) guidance on drug interactions and the HIV Drug Interactions Website www.hiv-druginteractions.org Examples of which include: o Bosentan o Carbamazepine, oxcarbamazepine o Phenobarbital, phenytoin, primidone, topiramate o Rifampicin, rifabutin o Efavirenz o Griseofulvin o Products containing St. John's Wort (hypericum perforatum) o Lamotrigine – the FSRH recommend that starting hormonal contraception in an individual using lamotrigine, should be done in consultation with the individuals GP or neurologist so that any dose adjustments required can be made ➢ Have had a cardiovascular event such as ischaemic heart disease, stroke or TIA since starting a POP or if when previously used a POP.
Cautions (including relevant actions to be taken)	The FSRH provide guidance on provision of contraception, based on patient's health conditions or characteristics. These are divided into 4 categories, which are listed below. When supplying desogestrel in individuals with conditions that are considered **UKMEC 2**, this should

	be done with caution and discussions should take place with the patient around their risks prior to a supply being made. Records of such discussions should be made for audit purposes. Where monitoring or follow up is appropriate, the individual should be informed of this need so that they raise it with their usual provider of ongoing contraception, when they access further supplies. **UKMEC Category 1**: A condition for which there is no restriction for the use of the method. **UKMEC Category 2:** A condition where the advantages of using the method generally outweigh the theoretical or proven risks. These are listed below. **UKMEC Category 3**: A condition where the theoretical risks usually outweigh the advantages of suing the method. The provision of the method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable. **UKMEC Category 4**: a condition which represents an unacceptable health risk if the method is used. **UKMEC Category 2 conditions are listed below.** The risks and benefits of desogestrel should be discussed with the individual if: ➢ They have had bariatric or other surgery resulting in malabsorption from the gastrointestinal tract. While this condition is **UKMEC 1**, there is insufficient evidence to inform whether contraceptive effectiveness of desogestrel is affected by bariatric surgery. Individuals may wish to consider effective non-oral contraception after bariatric surgery. If individuals are happy to proceed this should be documented. ➢ They have an organ transplant: o Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy o Uncomplicated

	➢ They have multiple risk factors for cardiovascular disease (CVD) (such as smoking, diabetes, hypertension, obesity and dyslipidaemias) when multiple major risk factors exist, the risk of CVD may increase substantially. ➢ They have hypertension with vascular disease (includes coronary heart disease presenting with angina, peripheral vascular disease presenting with intermittent claudication, hypertensive retinopathy and TIA. Hypertension can develop during progestogen use, individuals with hypertension should be closely monitored. ➢ They have a current and history of ischaemic heart disease and stroke (cerebrovascular accident, including TIA). These individuals will need follow up when they access further supplies from their local sexual health service or their GP as continuation of POP is **UKMEC 3**. Cohort studies do not show an increased risk of MI and stroke in users of POC (progestogen only contraception). ➢ Known dyslipidaemias. Increased levels of total cholesterol, LDL and triglycerides, as well as decreased levels of HDL, are known risk factors for CVD. Women with known, severe, genetic lipid disorders are at much higher lifetime risk for CVD and may warrant further clinical consideration. ➢ Venous thromboembolism (VTE) o History of VTE (includes DVT (deep vein thrombosis) and PE (pulmonary embolism)). o Current VTE (on anticoagulants) There is no direct evidence on the use of POC among women with DVT/PE on anticoagulant therapy. Although evidence on the risk of VTE with the use of POC is inconsistent in otherwise healthy women, any small increased risk is substantially less than that with the combined oral contraceptive (COC). o Major surgery with prolonged immobilization (includes major elective surgery >30 minutes duration and all surgery on the legs, or surgery which involves prolonged

	immobilization of a lower limb. ➢ Known thrombogenic mutations e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies. ➢ Cardiomyopathy with impaired cardiac function. An individual who is not on cardiac medication can be considered as having normal cardiac function. No direct evidence exists on the safety of POC among women with cardiomyopathy. Limited indirect evidence from non-comparative studies of women with cardiac disease demonstrates few cases of hypertension, thromboembolism and heart failure in women with cardiac disease using POP. ➢ Cardiac arrhythmias – atrial fibrillation ➢ Headache: o Migraine with aura, at any age o History (≥5 years ago) of migraine with aura, at any age Few studies have specifically assessed migraine in POC users, however, there is no evidence that the use of POC is associated with an increased risk of ischaemic stroke. ➢ Vaginal bleeding patterns: o Irregular pattern without heavy bleeding o Heavy or prolonged bleeding (includes regular and irregular patterns) o Unexplained vaginal bleeding Abnormal menstrual bleeding should raise suspicion of a serious underlying condition and be investigated appropriately. Bleeding patterns are often altered when using POC particularly in the initial months of use and may not settle with time. ➢ Breast conditions: o Undiagnosed mass/breast symptoms. Breast cancer is a hormonally sensitive tumour and therefore the prognosis of women with current or past breast cancer may be affected by hormonal methods of contraception o Carriers of known gene mutations associated with breast cancer e.g. BRCA1/BRCA2

	➢ Diabetes: Progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter therapeutic regimens however, diabetic patients should be carefully monitored during the first months of use. Limited evidence on the use of POC in diabetes suggests these methods have little effect on short term or long-term diabetes control (e.g. HbA1c levels), haemostatic markers or lipid profile. o Non-vascular disease: Non-insulin dependent and insulin dependent. o Nephropathy, retinopathy, neuropathy o Other vascular disease ➢ Gall bladder disease: o Symptomatic: treated by cholecystectomy, medically treated, and current disease o Asymptomatic ➢ Past COC related history of cholestasis. ➢ Benign liver tumours specifically focal nodular hyperplasia. There is limited direct evidence that hormonal contraception use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia. There is no evidence relating to use of hormonal contraception by women with other liver tumours. ➢ Inflammatory bowel disease (IBD) including Crohn's disease and ulcerative colitis. The risk for disease relapse among individuals with IBD using oral contraception (most studies do not specify whether it is POP or COC) does not increase significantly from that of non-users. Consideration should be given to their current disease status. Oral methods may be less reliable if there is significant malabsorption. Although the use of desogestrel is not contraindicated it may be less effective. Advise that Long Acting Reversible Contraception LARC is more efficacious. ➢ Rheumatoid arthritis. Risk of CVD is increased among women with rheumatoid arthritis. There is no evidence that POC are associated with reduced BMD (bone mineral density) or fragility

	fractures in women with rheumatoid arthritis. Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraception. (most studies do not specify whether it is POP or COC) ➢ Systemic lupus erythematosus (SLE) o No antiphospholipid antibodies o Positive antiphospholipid antibodies Women with SLE are at an increased risk of ischaemic heart disease, stroke and VTE. Positive antiphospholipid antibodies (aPL) is not itself a disease state and in the absence of manifestations of the aPL syndrome a stratification of risk with specialist advice, if necessary is recommended. **Other cautions:** ➢ Any child protection issues should be referred through appropriate channels as per actions if patient excluded. ➢ Any gender-based violence should be referred through appropriate channels. ➢ If individual has uncertainty about the safety of progestogen-only contraception despite counselling. ➢ They have already used Emergency Hormonal Contraception (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. ➢ Individuals at risk of pregnancy who have taken ulipristal acetate 30mg as EHC should be advised to wait for 5 days before commencing desogestrel, a pregnancy test must be taken 21 days after the last episode of Unprotected Sexual Intercourse (UPSI). ➢ 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. ➢ Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to

	chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking desogestrel. ➢ Current or previous depression dose not contraindicate the use of desogestrel. It is important to acknowledge that some individuals report mood changes during use of hormonal contraception. **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 (intrauterine device), IUS (intra uterine system) 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** ➢ For contraindications and cautions arising from drug interactions see FSRH Clinical Guidance: Drug Interactions with Hormonal Contraception January 2018 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ ➢ For antiretroviral interactions see Online HIV Drug Interaction Checker www.hiv-druginteractions.org ➢ Cautions - see BNF and SmPC
Action to be taken if the individual is excluded or declines treatment	➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given. ➢ Record the reason for decline in the consultation record. ➢ Refer the individual as soon as possible to local sexual health service or to their GP if appropriate and/or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services.
Arrangements for referral for medical advice	➢ Refer to GP or local sexual health clinic as appropriate. ➢ If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor should be consulted.

5. Description of treatment

Name, strength & formulation of drug	Desogestrel 75 microgram tablet
Legal category	POM – Prescription Only Medicine
Black triangle▼	No
Off-label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this document and may vary from the SmPC Where a drug is recommended off-label consider as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product license. ➢ Active venous thromboembolic disorder – see Cautions and UKMEC 2 conditions. ➢ Undiagnosed vaginal bleeding – see Cautions and UKMEC 2 conditions. ➢ The Quick Start use of desogestrel is outside of the licensed indication and should be documented in the patient record. ➢ It is outside the terms of the product licenses of all hormonal contraceptives (HC) for a Healthcare Professional to supply HC without being reasonably sure that the individual is not pregnant. However, the FSRH supports quick start of contraceptive method. **Quick Starting if Pregnancy Cannot be Excluded** **Quick start post EHC supply** When quick start is offered, the individual should be informed of the potential risks and advised of the need for a pregnancy test 21 days after last unprotected sex. **Quick Starting if Pregnancy Can be Excluded** **'Quick start' (standalone supply)** All methods of contraception can be started at any time in the menstrual cycle if a healthcare practitioner is reasonably certain that the individual is not currently pregnant or at risk of pregnancy. Healthcare practitioners can be reasonably certain that an individual 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

	an individual 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 individuals). ➢ They are using lactational amenorrhoea (LAM); i.e., 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 an individual 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 outside the first 5 days of a normal menstrual period.
Route / method of administration	Oral The tablet should be taken at the same time every day.
Dose and frequency of administration	➢ One single 75 microgram tablet daily, on a continuous basis and taken at the same time each day (if delayed by longer than 12 hours, contraceptive protection may be lost). ➢ Standard Start: ○ Desogestrel can be started on days 1-5 of a natural menstrual cycle, by day 5 after abortion or by day 21 after childbirth without requirement for additional contraceptive precautions. ➢ Quick Start: ○ Desogestrel can be started at any time after day 5 of a natural menstrual cycle with additional contraceptive precautions for the first 2 days of desogestrel use
Duration of treatment	3 months supply can be provided by community pharmacy.
Quantity to be supplied/administered	84 tablets (3x28) to be supplied at initiation. A further 3 months (84 tablets) can be supplied in exceptional circumstances e.g. pandemic related restrictions which prevent an individual accessing a continuing supply from their GP practice or Sexual Health Services.

Storage	This medicinal product does not require any special storage conditions. Medicines must be stored securely and in accordance with product. SmPC
Disposal	No special requirements.
Drug interactions	A detailed list of drug interactions can be found in the SmPC the BNF Further clinical guidance on drug interactions can be found https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ For antiretroviral interactions see Online HIV Drug Interaction Checker www.hiv-druginteractions.org Desogestrel is metabolised to the active metabolite etonogestrel. Etonogestrel is then metabolised by CYP3A enzymes. Contraindicated in individuals taking enzyme-inducing drugs or herbal products or within 28 days of stopping them. ➢ Examples of which include: ○ Bosentan ○ Carbamazepine, oxcarbamazepine, eslicarbazepine ○ Phenobarbital, phenytoin, primidone, topiramate ○ lamotrigine ○ rufinamide ○ Rifampicin, rifabutin ○ Griseofulvin ○ Products containing St. John's Wort (hypericum perforatum) ○ Modafinil ○ Aprepitant ○ Antiretrovirals: ritonavir, atazanavir, darunavir, fosamprenavir, lopinavir, nelfinavir, saquinavir and tipranavir ○ Non-nucleoside reverse transcriptase inhibitors: Efavirenz, nevirapine
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, and the BNF The list is not exhaustive The following side effects are common (affecting 1 in 10 patients). ➢ Altered mood, depressed mood, decreased sex drive (libido) ➢ headache

	➢ Nausea ➢ Acne ➢ Breast pain, irregular or no menstruation ➢ Changes in body weight The following side effects are uncommon (affecting up to 1 in 100 patients) ➢ Infection of vagina ➢ Difficulty wearing contact lenses ➢ Vomiting ➢ Hair loss ➢ Painful menstruation, ovarian cyst ➢ Tiredness ➢ Breast secretion or leakage has been reported. ➢ Vaginal bleeding may occur at irregular intervals. Irregular bleeding is not a sign that desogestrel is not working and in general no action is needed. **If bleeding is prolonged or heavy, individuals must consult their doctor.** The individual 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.
Reporting procedure of adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records. Alert a doctor in the event of a serious adverse reaction. Report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme.
Written information to be given to individual or their carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL). ➢ NHS conditions leaflet for Progestogen-only Pill available at https://www.nhs.uk
Patient or carer advice/follow up	Inform the individual or their carer: ➢ How to take the medication. ➢ To visit the NHS website on Progestogen-only contraceptive pill (POP) for more information. ➢ to read the PIL before taking the medication. ➢ That they may experience irregular bleeding. ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse. This includes any possible side effects not listed in the PIL ➢ to seek medical advice in the event of a severe adverse reaction.

	➢ if they experience signs of a blood clot e.g. severe pain or swelling in the legs, unexplained chest pain, breathlessness or cough to contact their doctor. ➢ if they develop severe stomach ache or yellowing of the skin, whites of the eyes or dark urine they should contact their doctor. ➢ to contact their GP in case of mood changes and depressive symptoms, including shortly after starting desogestrel. ➢ that they may need additional contraceptive precautions as follows: o Additional contraceptive precautions are not required if desogestrel is started up to and including day 5 of the menstrual cycle; if started after this time, additional contraceptive precautions are required for 2 days. o 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. o Desogestrel can be taken immediately when starting or restarting desogestrel as quick start after levonorgestrel EHC (LNG-EC), additional contraception is required for 48 hours. o Treatment with desogestrel should be delayed for 5 days following administration of UPA-EC. Additional contraception should be advised for the 5 days and for the 48 hours once desogestrel commenced. o 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. o After pregnancy (includes those who are breast feeding): up to day 20 no additional contraceptive method required, from day 21 advise additional contraceptive method for first 48 hours. o Following termination of pregnancy, miscarriage or ectopic pregnancy, 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. ➢ promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STI's. Visit www.friskywales.org for more information on accessing advice and testing. ➢ if pregnancy can't be excluded that they take a pregnancy test 21 days after the last episode of UPSI (unprotected sexual intercourse). ➢ to return to the pharmacy or GP/sexual health clinic if they have any problems or questions about the treatment. ➢ Vaginal bleeding may occur at irregular intervals. There may be slight staining which may not require a pad, or heavier bleeding which may look like a period and they may need to wear sanitary

	products. They may not have any bleeding at all. Irregular bleeding is not a sign that desogestrel is not working and in general no action is needed. ➢ If changes to bleeding patterns extend beyond the first 3 months to return to pharmacy or visit GP/sexual health clinic. ➢ Insert links to local sources of information and local sexual health service within local health board below:
Special considerations / additional information	Inform the individual or their carer: ➢ How to deal with a "**missed dose**" o A pill is missed if taken >12 hours late (>36 hours after the last pill was taken). o The missed pill should be taken as soon as remembered. If more than one pill has been missed, **only** one pill should be taken. o The next pill should be taken at the usual time. This may mean that two pills are taken in 1 day. o Additional contraceptive precautions (condoms or avoidance of sex) are advised for 2 days (48 hours) after correct pill-taking has restarted. o Emergency contraception is indicated if unprotected sexual intercourse occurred after the missed pill and within 48 hours of correct pill-taking. ➢ 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 medications which may cause diarrhoea and/or vomiting (e.g. laxatives) may 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. ➢ If severe watery diarrhoea occurs soon after taking deogestrel they should be advised to take another pill as soon as possible. The time at which the replacement pill is taken will determine if additional contraceptive precautions are required, see "missed dose" ➢ If abdominal pain with amenorrhoea (absence of periods) occurs they must visit the GP/sexual health clinic. Protection against ectopic pregnancy with traditional progestogen only pills is not as good as with combined oral contraceptives, because of the risk of ovulation. Desogestrel inhibits ovulation however, ectopic pregnancy should be taken into consideration. ➢ If attending a GP or other healthcare professional for any illness they should make them aware that they are using desogestrel.

Records	The consultation details must be recorded in Choose Pharmacy as prompted at the time of the consultation. Where the Choose Pharmacy platform is not available records, must be made to document the consultation, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy Contraception module as soon as practically possible and by the end of the next working day. ➢ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements see https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/information-governance-alliance-iga ➢ All records should be clear, legible and contemporaneous. ➢ A blood pressure and BMI should be documented at initiation and after 3 months if additional supply. as per NICE guidance http://www.nhsdirect.wales.nhs.uk/LiveWell/BMICalculator/ A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.

Appendices

Appendix A: *Key references*

- Summary Product Characteristics SmPC. Available from: Home - electronic medicines compendium (emc) Last accessed on 10th October 2022) (https://www.medicines.org.uk)
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Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the Supply of:
Desogestrel 75 microgram tablet Progestogen-Only Contraceptive Pill (POP) by community pharmacists under the Clinical Community Pharmacy Service: Bridging and Quick Start Contraception service commissioned by

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD. Only pharmacists with authorised access under the service specification with

can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this document, the professional operating the PGD confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist.

Name and address of Pharmacy:

For registered professional

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct.

Name of registered pharmacist	Signature	GPhC number	Date

A signed copy of this form must also be returned to:
Primary Care Services
Floor 3, Matrix House
Northern Boulevard
Matrix Park
Swansea Enterprise Park
Swansea
SA6 8BX

E-mail: nwssp-primarycareservices@wales.nhs.uk
Fax: 01792 860481