Health and Social Care

Department of Health
An Roinn Sláinte
Männystrie O Poustie
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Strategic Planning and Performance Group

Pharmacy First for help with everyday health conditions

Patient Group Direction (PGD)

Supply of Desogestrel 75microgram tablets via the Pharmacy First Emergency Hormonal Contraception (EHC) Service

Version v01.00

Valid from 1st May 2022 – 30th April 2024

Review date 1st March 2024*

*(*or earlier in event of changes to any related guidance or withdrawal of Pharmacy First Service)*

This patient group direction must be agreed to and signed by all pharmacists involved in its use. The PGD must be easily accessible in the community pharmacy.

Purpose of this Patient Group Direction

This PGD covers the supply of desogestrel 75microgram tablets i.e. progestogen only contraceptive pill via the SPPG Pharmacy First Emergency Hormonal Contraception (EHC) Service

Pharmacy First Service is available from community pharmacies in Northern Ireland contracted to provide the service.

Change history

Version number	Change details	Date
V01.00	➢ New SPPG PGD template for the supply of **desogestrel 75microgram tablets** via the Pharmacy First Emergency Hormonal Contraception (EHC) service	1st May 2022

Patient Group Direction (PGD) for supply/administration of

Desogestrel 75microgram tablets	**POM**

1. Staff Characteristics

Qualifications	Pharmacists currently registered with the Pharmaceutical Society of Northern Ireland
Specialist competencies or qualifications	Pharmacist must be: 1. Working as a community pharmacist in a pharmacy contracted to provide the Pharmacy First Service. 2. Familiar with the relevant Summary of Product Characteristics for the medicines that may be supplied via this Patient Group Direction (PGD). 3. Familiar with and adhere to relevant Pharmaceutical Society of Northern Ireland standards and guidance 4. Have completed all the required training modules/courses outlined in the service specification. All pharmacists are personally accountable for their practice and must be competent to work under PGD. In the exercise of professional accountability there is a requirement to maintain and improve professional knowledge and competence. The pharmacists must be 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 up to date with child protection training and familiar with local and national child protection guidelines and local contacts to report information if required. All pharmacists must be familiar with the SPC for desogestrel 75microgram tablets. 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 training & education	The pharmacist should be aware of any change to the recommendations for the medicine that may be supplied via this PGD. The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification and Guidance. It is the responsibility of the individual to keep up-to-date with

	continued professional development and to work within the limitations of individual scope of practice.

2. Clinical Condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Female patient requiring access to **Bridging Contraception*** **Bridging contraception is a short-term supply that can be offered to allow a patient sufficient time to access their GP or other sexual health service for a longer term, ongoing supply. This bridges the gap between emergency contraception and starting on a regular method of contraception.*
Criteria for inclusion	• Female patients aged 13 – 55 years who wish to commence a **progestogen only contraceptive pill (POP)** 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. • POP can only be supplied as part of a Pharmacy First consultation for EHC. • No contraindications to the medication. • Informed consent given.
Criteria for exclusion (refer to current SPCs and BNF)	• Informed consent not given. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines • Individuals 16 years of age and over and assessed as lacking capacity to consent. • 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 POP is supplied). • If very early pregnancy cannot be excluded, i.e. pregnancy test negative but other episodes of UPSI within previous 2 weeks, POP can still be supplied as there is no evidence that taking POP in very early pregnancy is associated with pregnancy loss or birth abnormalities. A follow-up pregnancy test no sooner that 21 days after last UPSI is advised. • Has unexplained vaginal bleeding. • Currently using regular hormonal contraception (i.e. reason for

	EHC was missed pill). • Already received the maximum 3 month supply of POP from community pharmacy via the Pharmacy First Service within the previous 12 weeks. • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics • 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). • Individuals 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. • Acute porphyria. **Cardiovascular Disease** • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic first attack only if taking the method when the event occurred. **Cancers** • Current or past history of breast cancer. • Benign liver tumour (hepatocellular adenoma). • Malignant liver tumour (hepatocellular carcinoma). **Gastro-intestinal conditions** • Severe decompensated cirrhosis. • Any bariatric or other surgery resulting in malabsorption. Interacting medicines (other than enzyme inducers) – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk
Cautions including any	• Safeguarding - Assessed as not competent to consent to treatment • Safeguarding - Any child welfare issues should be referred through appropriate channels

relevant actions to be taken	• Safeguarding - Any gender based violence should be referred through appropriate channels • Has uncertainty about the safety of POP despite counselling • Current early pregnancy cannot be excluded, i.e. pregnancy test negative but UPSI within previous 2 weeks - POP can still be supplied as there is no evidence that taking POP in very early pregnancy is associated with pregnancy loss or birth abnormalities. A follow-up pregnancy test no sooner that 21 days after last UPSI is advised. • Already used EHC since their last menstrual period – if pregnancy is suspected, this should be excluded before POP is supplied. If pregnancy cannot be excluded, e.g. negative pregnancy test but UPSI in the previous 2 weeks, POP can still be supplied (see above). • 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. In such cases POP can be supplied to 'bridge' the gap between EHC and restarting their usual contraception. • 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 POP is not contraindicated it may be less effective. Advise that Long Acting Reversible Contraception (LARC) is more efficacious although POP may still be considered to 'bridge' the gap between EHC and starting another method of contraception. • 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 POP is chosen then an additional barrier method of contraception is advised. See FSRH Guidance** • Cautions - see BNF and Summary of Product Characteristics
Action if patient is	• Explain the reasons for exclusion to the individual and document in

excluded or declines treatment	the consultation record. • Record reason for decline in the consultation record. • Offer alternative contraceptive advice and refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, form & strength of medicine	Desogestrel 75 micrograms tablet
Legal status	POM - Prescription only medicine to be supplied *P medicine should not be supplied via this PGD*
Is the indication within terms of 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 certain contraceptive methods, including the Progestogen Only Pill, as described in their Clinical Guideline because the benefits of establishing reliable contraception outweigh the very low risk associated with the use of POP where pregnancy cannot be excluded. The patient should be informed of this and use of POP outside licensed indications should be documented in patient's clinical record. 'Quick starting contraception' Quick starting contraception includes: - Starting contraception at a time other than the beginning of the menstrual cycle, but it is reasonably certain that there is no risk of pregnancy. - Starting contraception at a time other than the beginning of the menstrual cycle and there is a potential risk of very early pregnancy from recent UPSI (but it is too early to exclude pregnancy using a pregnancy test). Quick starting in this situation is appropriate if a woman considers it likely that she will continue to be at risk of pregnancy or if she wishes to avoid delaying commencement of contraception. After Levonorgestrel administration, POP can be quick started immediately.

	After Ulipristal acetate administration, the individuals should wait 5 days before quick starting POP. 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.
Route/Method of administration	Oral
Off label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare FSRH is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes inclusion criteria, exclusion criteria and dosage regimens which are outside the market authorisation for many of the available products but which are included within FSRH guidance. Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence.
Dosage and frequency of administration	• Once a day, at the same time each day. • To be taken continuously without a break between packs. • If started on day 1-5 of the menstrual cycle there is no need for additional protection. • If started at any time after day 5 additional precautions are then required for **48 hours after starting**, i.e. use of condoms. If unprotected intercourse has occurred prior to starting POP, 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 hormonal contraception, additional contraception is required for 48 hours, i.e.

	use of condoms. • Treatment with desogestrel should be delayed for 5 days following administration of ulipristal emergency hormonal contraception. Additional contraception for 48 hours should be advised once desogestrel commenced. • 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.
Duration of treatment	• Three months' supply from community pharmacy
Quantity of supply	• 84 tablets (3 x 28)
Disposal	Advise return of excess medication to community pharmacy for safe disposal.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: https://www.medicines.org.uk/emc/ or the BNF https://bnf.nice.org.uk/ and in the FSRH guidance Drug Interactions with Hormonal Contraception Guidance
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: https://www.medicines.org.uk/emc/ and BNF https://bnf.nice.org.uk/ The following side effects are common with POP use (but may not reflect all reported side effects): • Irregular bleeding, amenorrhoea • Nausea and vomiting • Breast tenderness • Dizziness, headache and depression • Changes in body weight and libido.

	The patient must be advised to contact the place of issue or another appropriate healthcare professional: • If they are concerned about any changes in their health that they feel may be due to POP • If they are concerned about any circumstance that may affect the efficacy of POP • To report any adverse reactions as soon as possible.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's PMR. • Report any adverse reactions in line with the pharmacy's adverse incident reporting standard operating procedure.
Written information and further advice to be given to patient	• The mode of action, efficacy and failure rate of the treatment. Practical advice on how to take one tablet every day e.g. patient could store POP with toothbrush/ makeup and take one every day when getting ready. • Advantages and disadvantages of taking a POP. • How to take the POP: treatment to commence immediately after levonorgestrel emergency hormonal contraception, or 5 days after ulipristal emergency hormonal contraception. Choose a time of day to take POP at. However, it can be taken up to 12 hours after the usual time. • Possible side-effects. Patient may notice a few side effects in the first week or so, such as headaches, mood swings, nausea, sore breasts, but these are usually very mild and pass very quickly. • Expected bleeding pattern. Patient may notice a change in their period i.e.: 1) Continues to be regular but be lighter than normal 2) After a few months period may stop altogether 3) Periods may be irregular. Patients are advised to continue with POP for the initial 3 months, but if still not happy with what it has done to their period, a change to a different method of contraception may be preferred. • The need, length and method of extra precautions (as above). • The need and timing of a pregnancy test (if required with "quick starting"). • How to deal with a "missed pill": take the next pill as soon as it is remembered and carry on with the pill at the correct time. If the pill was more than 12 hours overdue then patient is not protected and should consider emergency contraception if unprotected sexual intercourse has taken place. Continue normal pill-taking but must also use another method of contraception, such as a condom, for

	at least 48 hours (but may be best to avoid for up to 7 days to avoid ovulation). • 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 a POP. • Advise that it is possible that medications that induce diarrhoea and/or vomiting (e.g. laxatives) could reduce the effectiveness of a POP. • If vomiting occurs within 2 hours of taking a tablet, another tablet 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 a POP. • Sexually transmitted infections: advise on STI risk, regular STI screening and condom use encouraged. • Weight gain: POP does not cause weight gain. If patient notices their appetite increasing in the first few days, they should be advised to avoid eating more than normal as their appetite should soon return to normal. **Written Advice or directed to relevant online information:** • Details of Sexual and Reproductive Services and how to contact them • The manufacturer's Patient Information Leaflet should be given.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction.

4. Referral Arrangements and Audit Trail

Records / Audit	Record:
	• The consent of the individual and
	  ○ If individual is less than 13 years of age record action taken
	  ○ If individual is less than 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ If individual over 16 years of age and not competent, record action taken
	• Name of individual, address, date of birth
	• GP contact details where appropriate
	• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight
	• Any known medication allergies
	• Name of the pharmacist operating under the PGD
	• Name of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied
	• Advice given, including advice given if excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns
	• Any referral arrangements made
	• Any supply outside the terms of the product marketing authorisation
	• Recorded that administered/supplied via Patient Group Direction (PGD)
	Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.
	
	All records should be clear, legible and contemporaneous.
	
	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

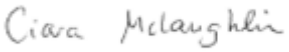
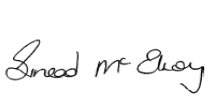
5. Key references

Key references (accessed 24th January 2022)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - March 2017, amended December 2020 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - December 2017, reviewed 2019 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines

Patient Group Direction (PGD) for supply/administration of

Desogestrel 75microgram tablets	**POM**

PGD Template Development

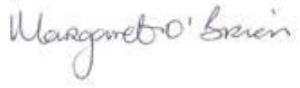
	Name	Signature	Date
Clinician	Dr Rachel Coyle Public Health Consultant		25/02/2022
Clinician	Dr Ciara McLaughlin SPPG GP Medical Adviser		10/02/2022
Pharmacist	Sinead McElroy SPPG Pharmacy Adviser		10/02/2022

This PGD has been reviewed and updated by the Regional PGD Review Group:

Name	Designation
Siobhan O'Hare-Smith	SPPG Pharmacy Adviser

SPPG Authorisation for use in Community Pharmacies in Northern Ireland

This Patient Group Direction has been approved for use by the Strategic Planning and Performance Group by:

Primary Care approval			
Role	**Name**	**Sign**	**Date**
SPPG Head of General Medical Services	Dr Margaret O'Brien		15/04/2022
SPPG Head of Pharmacy & Medicines Management	Joe Brogan MPSNI		24/03/2022
SPPG Clinical Governance Lead	Sharon Gallagher Deputy Secretary of Health		18/05/2022

Patient Group Direction (PGD) for supply/administration of

Desogestrel 75microgram tablets	**POM**

Authorisation Page – Community Pharmacies

Organisations using PGDs must designate an appropriate person within the organisation to ensure that only fully competent, qualified and trained healthcare professionals operate within a PGD.
This page must be completed by pharmacists who will operate under the PGD i.e. pharmacists working in the community pharmacy

Name of Community Pharmacy: .....…….....

The Pharmacy Manager / Contractor on behalf of the independent pharmacy contractor has accepted the responsibility to ensure that:

1. The named pharmacists (listed on the signature sheet) have received the appropriate training as detailed in the PGD.
2. Only fully competent, qualified and trained pharmacists operate within these directions on behalf of the community pharmacy.
3. The content of the Patient Group Direction is agreed on behalf of the independent pharmacy contractor.
4. Authorised staff should have access to a copy of the PGD indicating their authorisation to work within the scope of the PGD.

Signature ……..... **Date**……

Name (please print).....

Patient Group Direction (PGD) for supply/administration of

Desogestrel 75microgram tablets	**POM**

Authorisation Page - Individual Signature Sheet

The following registered pharmacists are allowed to operate under this PGD

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD. I understand that PGDs do not remove inherent professional obligations or accountability and it is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the "Code for pharmacists in Northern Ireland".

Name of Professional (PRINT)	Signature	Date

Print extra copies of this page as need be. Page __ of __