



This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the supply of

Desogestrel 75mcg
Norethisterone 350mcg

By registered health care professionals for

Female Clients requesting contraception

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD 17

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021
2	PGD 17 and 124 combined and minor changes made	January 2023

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job Title	Name	Signature	Date
Deputy for Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A
Medical Director			
Director of Nursing			

5. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	<ul style="list-style-type: none"> Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises
Initial training	<ul style="list-style-type: none"> Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD Local training in the use of PGD's
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

6. Clinical Conditions

Clinical condition or situation to which this PGD applies	Contraception
Inclusion criteria	<ul style="list-style-type: none"> Individual (age from menarche to 55 years) presenting for contraception Fraser competent
Exclusion criteria (continued)	<p>This PGD is to be used in conjunction with current faculty guidance:</p> <ul style="list-style-type: none"> Consent not given Any UKMEC level 3 or 4 Anyone with 2 or more level 2s Individuals under 16 years of age and assessed as not competent using Fraser Guidelines Individuals 16 years of age and over and assessed as lacking capacity Known or suspected pregnancy Known hypersensitivity to the active ingredient or to any constituent of the product –see Summary of Product Characteristics

<p>Exclusion criteria (continued)</p>	<ul style="list-style-type: none"> • Individuals using enzyme-inducing drugs /herbal products or within 4 weeks of stopping them • Acute porphyria • Unexplained vaginal bleeding not evaluated <p>Cardiovascular disease</p> <ul style="list-style-type: none"> • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic attack only if taking the method when the event occurred <p>Cancers</p> <ul style="list-style-type: none"> • Current or past history of breast cancer • Malignant liver tumour <p>Gastrointestinal Conditions</p> <ul style="list-style-type: none"> • Benign liver tumour • Severe decompensated liver cirrhosis • Conditions causing severe malabsorption, such as bariatric surgery <p>Interacting medicines see BNF, or individual product SPC</p>
<p>Cautions (including any relevant action to be taken)</p>	<ul style="list-style-type: none"> • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented • If individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow local safeguarding policy • Discuss with doctor the medical condition or medication of which the healthcare professional is unsure or uncertain • Consideration should be given to the current disease status of those with severe malabsorption syndrome. Although POP is not contraindicated it may be less effective and so these individuals should be advised about (Long Acting Reversible Contraception (LARCS) • Women should be advised that it is possible that medications that induce diarrhoea or vomiting could reduce the effectiveness of POP • Offer LARCS to individuals with medical conditions for whom pregnancy presents an unacceptable risk <p>A detailed list of cautions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk</p>
<p>Arrangements for referral for medical advice</p>	<p>Patient should be referred to a more experienced clinical practitioner for further assessment</p>

Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated

7. Details of the medicine

Name, form and strength of medicine	<ul style="list-style-type: none"> • Desogestrel 75mcg tablets • Norethisterone 350mcg tablets <p>This PGD does not restrict which brands can be supplied</p>
Legal category	Prescription Only Medication (POM)
Indicate any <u>off-label use</u> (if relevant)	<p>Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the SPC</p> <ul style="list-style-type: none"> • Quick start
Route/method of administration	Oral
Dose and frequency	<ul style="list-style-type: none"> • One pill daily on a continuous basis, ideally at the same time each day, so the interval between tablets is about 24 hours • If started on day 1-5 of the menstrual cycle there is no need for additional protection • The POP can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional precautions are required for 48 hours after starting and advise to have a follow up pregnancy test at 21 days • When restarting POP as quick start after Levonorgestrel emergency contraception, additional precautions are required for 48 hours • After using Ulipristal acetate emergency contraception refer to FSRH guidance • See FSRH guidance for more specific advice
Quantity to be supplied	<ul style="list-style-type: none"> • First supply 3 months (1 box, 3 month supply of 3x28: total 84 tablets) • Repeat supply 6-12 months
Maximum or minimum treatment period	<p>Minimum: 1 box (3 month supply)</p> <p>Maximum: 4 boxes (12 month supply)</p>
Storage	Room temperature in a locked cupboard

Adverse effects	<p>Common side effects:</p> <ul style="list-style-type: none"> • Acne • Depression • Headache • Irregular bleeding, prolonged bleeding or amenorrhoea • Loss of libido • Mood swings • Nausea • Skin reactions • Weight gain <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk</p>
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

8. Patient information

Verbal/Written information to be given to patient or carer	<ul style="list-style-type: none"> • Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

9. Appendix A

References
<ol style="list-style-type: none"> 1. British National Formulary (BNF) available online: https://bnf.nice.org.uk 2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk 3. Current Health Care Professions Council standards of practice 4. General Pharmaceutical Council standards 5. Electronic medicines compendium available online: https://www.medicines.org.uk 6. Faculty of Sexual and Reproductive Healthcare Guideline on Progesterone only Pills, Aug 2022 7. Faculty of Sexual and Reproductive healthcare Clinical Guideline: quick Starting Contraception, April 2017 8. Faculty of Sexual and Reproductive healthcare UK Medical Eligibility Criteria, 2016

10. Appendix B

Health professionals agreed to practice
<ul style="list-style-type: none"> • Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves