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 administration of

Insertion of Etonogestrel 68mg subdermal implant for contraception (e.g. Nexplanon®)

By registered health care professionals for

Contraception

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

PGD NUMBER 25

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021
2	Review with minor wording changes	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 to 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	• 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	• 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	Long acting reversible contraception
Inclusion criteria	• Individual (age from menarche to 55 years) presenting for contraception who has no contraindications • Consent given • Where appropriate individuals requiring insertion of this subdermal contraceptive implant should also meet the inclusion criteria of lidocaine 1% PGD
Exclusion criteria (continued)	• Consent not given • 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 to consent • Anyone UKMEC level 3 or 4 • Anyone with 2 or more UKMEC level 2s • Known or suspected pregnancy • Known hypersensitivity to the active ingredient or any constituent of the product – see Summary of Product Characteristics

Exclusion criteria (continued)	• Acute porphyria • Unexplained vaginal bleeding not evaluated **Cardiovascular disease** • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic attack • Individuals with multiple risk factors for cardiovascular disease • Hypertension with vascular disease **Cancers** • Current or past history of breast cancer • Malignant liver tumour **Gastrointestinal conditions** • Severe decompensated cirrhosis • Benign liver tumour **Interacting Medications** • Individuals using enzyme inducing drugs/herbal products or within 28 days of stopping them. • See current British national Formulary (BNF) or individual Summary of product Characteristics.
Cautions (including any relevant action to be taken)	• 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 • If the individual is taking any anticoagulant therapy, an experienced clinician should perform the procedure due to the risk of bleeding, a pressure bandage should be applied after insertion (see FSRH guidance) • Discuss with doctor and medical condition or medication of which the healthcare professional is unsure or uncertain 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
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
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	• 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	Etonogestrel 68mg subdermal implant
Legal category	Prescription Only Medicine (POM)
Indicate any <u>off-label use</u> (if relevant)	• Best practice is given by the FSRH and is used for guidance and may vary form SPC • Insertion in individuals under 18 years of age • Quick starting
Route/method of administration	• Superficial subdermal implant inserted , preferably non-dominant arm, under aseptic conditions • Follow manufacture and FSRH current guidance
Dose and frequency	• Insert once every 3 years • Insert between day 1 and 5 of the menstrual cycle with no need for additional precautions • The implant may be inserted or reinserted at any time as quick start if it is reasonable certain that the individual is not pregnant. Additional contraception is the required for 7 days after insertion, advise a pregnancy test at 21 days after insertion • If the individual has an implant in situ, which has been in place for over 3 but less than 4 years the implant can be removed and replaced. A pregnancy test should be performed and if negative replace the implant and advise additional contraception is then required for 7 days after insertion with a repeat pregnancy test at 21 days • If inserting after levonoegestrel emergency contraception then, barrier contraception is required for 7 days and a pregnancy test at 21 days • After the use of ulipristal acetate emergency contraception refer to the FSRG guidance Refer to FSRH guidance for more specific advice
Quantity to be administered	One subdermal implant
Maximum or minimum treatment period	One episode of care
Storage	At room temperature in a locked cupboard

Adverse effects	The implant is generally well tolerated. The main reported side effects include: • Acne • Breast tenderness • Fluid retention • Headache • Irregular bleeding • Local scarring • Mood changes • Nausea • Reduced libido There have been rare repots of local and distant migration of Nexplanon® implants. If an implant cannot be located at the insertion site, this should be referred and investigated. Other possible complications of insertion and removal include local reaction, nerve damage and deep insertion 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
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	• 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

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. FSRH progesterone only implant guidance, available at : https://www.fsrh.org/documents/cec-ceu-guidance-implants-feb-2014/2fsrh-guideline-progestogen-only-implant-feb-2021.pdf
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
1. Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor 2. 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