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 or supply of

Medroxyprogesterone acetate 160mg per ml
Sayana Press 104mg/0.65ml

By registered health care professionals for

Contraception

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

PGD NUMBER 44

1. Change history

Version number	Change details	Date
1	Original PGD ratified	November 2021

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
Medical Director			
Chief pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. 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 • Specific training in sexual health and/or contraception, or equivalent experience
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 PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
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

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Contraception
Inclusion criteria	• Females of childbearing potential with a UKMEC score 2 or less • In adolescents aged 13-18 years when other long term methods of contraception are inappropriate
Exclusion criteria	• Known or suspected pregnancy • Known hypersensitivity to any constituent of the injection. • Under 16 years of age and assessed as not Fraser competent • A history of breast cancer within the last 5 years • Liver tumour and hepatic impairment • Acute porphyria • Severe Arterial disease • Undiagnosed vaginal bleeding
Cautions (including any relevant action to be taken)	• History during pregnancy in disturbances of lipid metabolism • History during pregnancy of deterioration of otosclerosis • History during pregnancy of pruritis • Severe liver disease and recurrent cholestatic jaundice • In women with risk factors for osteoporosis, a method of contraception other than medroxyprogesterone should be considered
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

8. Details of the medicine

Name, form and strength of medicine	Medroxyprogesterone acetate 160mg per ml Sayana Press 104mg/0.65ml
Legal category	Prescription Only Medicine (POM)
Indicate any <u>off-label use</u> (if relevant)	Injections may be given at 8 – this should be 10 - 12 weeks if problematic bleeding in first 3 cycles
Route/method of administration	Subcutaneous injection injected into anterior thigh or abdomen

Dose and frequency	• Single pre-filled injection (104mg/0.65ml) on day 1-5 of the menstrual cycle with no need for additional protection. • SC-DMPA can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional precautions are then required for 7 days after starting and advise to have follow up pregnancy test at 21 days if there was a risk of pregnancy • When starting or restarting SC-DMPA as quick start after levonorgestrel emergency contraception, additional contraception is required for 7 days and follow up pregnancy test at 21 days is required. • In line with FSRH guidance individuals should delay starting or restarting hormonal contraception for 5 days following use of ulipristal acetate for emergency contraception. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised for a further 7 days and follow up pregnancy test at 21 days is required. • SC-DMPA dose should be repeated 13 weeks after the last injection. • If required a repeat injection can be given up to 14 weeks after the previous dose with no additional contraceptive precautions. • If required on an occasional basis, SC-DMPA injection may be repeated as early as 10 weeks after the last injection. • If the interval from the preceding injection is greater than 14 weeks and unprotected sexual intercourse (UPSI) has occurred the injection may be administered/supplied - the professional administering the injection should refer to FSRH current guidelines for advice on the need for additional contraception and pregnancy testing. • For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines.
Quantity to be administered and/or supplied	• If being administered under this PGD a single dose (one pre-filled syringe) is to be administered per episode of care. • If for self-administration supply up to twelve months supply (up to 4 pre-filled 0.65 ml pre-filled syringes).
Maximum or minimum treatment period	• For as long as individual requires SC-DMPA and has no contraindications to its use. • Note - in individuals of all ages, careful re-evaluation of the risks and benefits of treatment should be carried out in those who wish to continue use for more than 2 years. In particular, in individuals with significant lifestyle and/or medical risk factors for osteoporosis, other methods of contraception should be considered prior to use of SC-DMPA.
Storage	Room temperature

Adverse effects	Refer to SPC of relevant product and current British National Formulary for further information • Alopecia • Breast abnormalities • Depression • Dizziness • Fluid retention • Insomnia • Menstrual cycle irregularities • Nausea • Sexual dysfunction • Skin reactions • Weight changes **Reduction in bone mineral density is greater with increasing duration of use. The loss is mostly recovered on discontinuation**
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

9. 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	• Full counselling backed by patient information leaflet required before administration – likelihood of menstrual disturbance and the potential for a delay in return to full fertility • Delayed return of fertility and irregular cycles may occur after discontinuation of treatment but there is no evidence of permanent infertility

10. Appendix A

References
1. British National Formulary (BNF) available online: https://bnf.nice.org.uk 2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk 3. Current Health Care Professions Council standards of practice 4. General Pharmaceutical Council standards 5. The General Optical Council 6. Electronic medicines compendium available online: https://www.medicines.org.uk 7. Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit Guidance for Injectable Progesterones (CEU GUIDANCE) 8. Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria Document (UK MEC) 9. Family Planning Clinic Safeguarding Risk Assessment Tool

11. Appendix B

Health professionals agreed to practice
• 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