NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Patient Group Direction For The Initial And Repeat Administration Of Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) Injection By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from FSRH/SPS Patient Group Direction (PGD) Supply And/Or Administration Of Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) injection, Version 2.2 – Date Published July 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/SC-DMPA/1356	**Review Date:** October 2025 **Expiry Date:** April 2026	**Date Approved by NoS:** May 2023 (Amended August 2024) **Publication Date:** November 2024

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2.2 (Amended August 2024)

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/SC-DMPA/MGPG1356, Version 2	
Date of change	**Summary of Changes**	**Section heading**
	SPS Version 2.1 (September 2023) Unpublished by NoS	
August 2024	Transferred onto New Template.	
August 2024	Reference to NoS Appendix 1 and 2.	Authorisation
August 2024	Removed SPS advised training and added TURAS NoS PGD training link added.	Initial Training
August 2024	NICE Competency framework statement removed.	Competency assessment
August 2024	Added statements regarding child protection.	Criteria for inclusion
August 2024	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
August 2024	Statement added about gender based violence and welfare.	Cautions including any relevant action to be taken
August 2024	Healthy bone advice and hyperlink added.	Advice (Verbal)
August 2024	Added clinical systems utilised.	Records

FSRH/SPS

Change History	
Version and Date	**Change details**
Version 1.0 May 2020	New template.
Version 1.1 November 2020	Minor rewording and highlighting of contents cautions section relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan. Acute porphyria added to exclusion criteria.
Version 2.0 May 2023	Updated template (no clinical changes to expired V1).

Version and Date	Change details
Version 2.1 September 2023	Reworded section on cervical and breast cancer risk, in line with updated FSRH guidance. Updated references.
Version 2.2 July 2024	Statement added regarding a suggested link between the prolonged use of medroxyprogesterone acetate and a small increased risk of intracranial meningioma in line with FSRH statement. Added exclusion of meningioma as per SPC. Updated references. Updated SLWG.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by SPS/FSRH and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply/administer medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines supply/administer in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply/administer of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Heike Gleser	Signature		Date Signed	24/10/2024
Pharmacist	Findlay Hickey	Signature		Date Signed	19/09/2024
Nurse	Julia Penn	Signature		Date Signed	02/10/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		14/11/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells- Interim Chief Executive		20/11/2024

Version 2.2 – Approved for NoS from 20th November 2024

Date PGD template comes into effect:	May 2023
Review date	October 2025
Expiry date:	April 2026

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group (SLWG) in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in December 2022.

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

Name	Designation
Dr Cindy Farmer	Vice President, Professional Learning and Development Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Elaine Scott	Senior Quality Matron British Pregnancy Advisory Service (BPAS)
Kalpesh Thakrar	Lead Pharmacist British Pregnancy Advisory Service (BPAS)
Sim Sesane	CASH Nurse Consultant MSI Reproductive Choices
Tanya Lane	FSRH Faculty Registered Trainer, Registered Nurse MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Portia Jackson	Lead Pharmacist iCaSH, Cambridgeshire Community Services
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Alison Crompton	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service
Rosie Furner (Working Group Co-ordinator)	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service

1. Characteristics of staff

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with local policy. Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory. Have undertaken NoS PGD module training on TURAS Learn. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix 1 and Appendix 2) or complete an appropriate self-declaration of competence for relevant testing and/or treatment.
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Contraception.
Criteria for inclusion	• Individual (age from menarche to 50 years) presenting for contraception. • Informed consent given. • Aged 13 years and over. All individual under the age of 18 years - follow local young person's risk assessment or equivalent local process. • Individuals under 16 years of age may give consent for the administration of SC DMPA, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment.
Criteria for exclusion	• Informed 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. • Established pregnancy. Note-risk of pregnancy with a negative pregnancy test is not an absolute exclusion. • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics. • Unexplained vaginal bleeding suspicious of a serious medical condition, present before commencing the method • Acute porphyria **Cardiovascular Disease** • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic attack.

	• Individuals with multiple risk factors for cardio-vascular disease (such as smoking, diabetes, hypertension, obesity and dyslipidaemias). • Hypertension with vascular disease. **Cancers** • Current or past history of breast cancer. • Benign liver tumour (hepatocellular adenoma). • Malignant liver tumour (hepatocellular carcinoma) • History / diagnosis of meningioma. **Gastro-intestinal conditions** • Severe decompensated cirrhosis. **Interacting medicines** – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk
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 the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. • Any gender based violence, child protection and welfare issues or adult protection concerns should be referred through the appropriate channels. • Discuss with appropriate prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. • Individuals aged under 18 years, should not use SC-DMPA first line for contraception because of its effect on bone mineral density. SC-DMPA may be considered if all alternative contraceptive options are unsuitable or unacceptable. • Offer 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 a SC-DMPA is chosen then an additional barrier method of contraception is advised. See FSRH advice.

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. • Record reason for decline in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Medroxyprogesterone Acetate (e.g. Sayana Press®) 104 mg in 0.65mL injection (pre-filled syringe) **Note:** • This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to. • See http://www.mhra.gov.uk/spc-pil/ or http://www.medicines.org.uk for further information and further brand information including full details of adverse effects and interactions.
Legal category	POM
Route of administration	Subcutaneous injection. **Advice for administration:** • Shake the syringe vigorously before administration. • Ensure that the full injection is given. The medication should be injected slowly over approximately 5-7 seconds with the needle pointing downwards. • Inject into the upper anterior thigh or the anterior abdomen, avoiding bony areas or the umbilicus and areas of inflamed or broken skin. • Do not massage the site after the administration of the injection. **NOTE – if administering SC-DMPA the healthcare professional must only use a pre filled syringe from stock under this PGD and must not use any pre filled syringe which has been supplied by the individual/supplied to the individual.**
Off label use	Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).

	This PGD specifically includes inclusion criteria and dosage regimens which are outside the market authorisation for many of the available products but which are included within FSRH guidance: • Supply and administration at 10 weeks after last injection. However administration at under 13 weeks from the last administration should not be routinely or consistently undertaken and 13 week intervals should be advised. • Supply and administration up to 14 weeks after last injection. • Supply and administration after five days postpartum if not breast feeding/before six weeks postpartum if breast feeding. FSRH guidance supports the use of SC-DMPA any time after childbirth for both breastfeeding and non-breastfeeding individuals. 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.
Dose and frequency of administration	• 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.
Duration of treatment	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.
Quantity to be 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).

Storage	Medicines must be stored securely according to national guidelines.
Drug interactions	The efficacy of SC-DMPA is **not** reduced with concurrent use of enzyme-inducing drugs. All concomitant medications should be checked for interactions. A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) | FSRH/ Refer to a prescriber if any concern of a clinically significant drug interaction.
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: www.medicines.org.uk and BNF www.bnf.org The following possible adverse effects are commonly reported with SC-DMPA (but may not reflect all reported adverse effects): • Headache • Injection site reactions including possible irreversible skin dimpling or indentation at injection site • Disturbance of bleeding patterns • Changes in mood • Weight change • Loss of libido • Delay in return to fertility after stopping the medication • Association with a small loss of bone mineral density which is recovered after discontinuation of the injection • The available evidence suggests a possible association between current or recent use of hormonal contraception (including progestogen-only injectables) and a small increase in risk of breast cancer; absolute risk remains very small. • There is a weak association between cervical cancer and use of DMPA for 5 years or longer. Any increased risk appears to reduce with time after stopping and could be due to confounding factors.

	• Individuals should be advised that evidence suggests a link between the prolonged use of medroxyprogesterone acetate and a small increased risk of intracranial meningioma requiring surgery.
Additional facilities and supplies	• Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000).
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers 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 medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	• Provide patient information leaflet (PIL) provided with the original pack. • Explain mode of action, side effects, risks and benefits of the medicine • Demonstrate to individual how to self-administer according to manufacturer's instructions/signpost to video tutorial. • Advise that while rare, anaphylactic reaction is possible with both first and subsequent exposures. It is therefore recommended that users are advised to ensure there is a competent adult present at the time of self-administration who is aware of the signs of anaphylaxis that they should call for emergency help at the time of onset of any relevant symptoms. • Advise individual on safe disposal of sharps according to local policy. • Advise individual about need to return for repeat injection if they experience any difficulty with administration. • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Ensure the individual has contact details of local service/sexual health services.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • Individual to seek further advice if they have any concerns.

	• Healthy bone advice (a well-balanced, calcium rich diet, regular weight-bearing exercise, get outdoors and avoid excessive alcohol and smoking) ○ Bone Health for All Advice • Return for review annually.

Records	**Record:**
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 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 and family history.
	• Any known allergies
	• Name of registered health professional
	• Name of medication supplied/administered
	• Date of supply and whether administered, if administered record site of administration
	• Dose supplied/administered
	• Quantity supplied including batch number and expiry date in line with local procedures.
	• Advice given, including advice given if excluded or declines treatment
	• That the individual has been assessed as competent to self-administer and trained to self-administer
	• That the individual has been supplied with the required equipment, including sharps bin for disposal
	• Individual has been advised on the dates/s for repeat self-injection and/or next appointment as required.
	• 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 supply/administration is 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. Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate 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.

4. Key references

Key references (accessed October 2022, July 2023, April 2024 and June 2024)	• 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: Progestogen-only Injectable Contraception (December 2014, amended July 2023) Progestogen-only Injectables | FSRH • FSRH CEU Statement: Self-Administration of Sayana Press® (September 2015) FSRH CEU statement: Self-Administration of Sayana Press® (September 2015) | FSRH • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) | FSRH • Faculty of Sexual and Reproductive Health CEU Statement: Response to new study by Roland et al (2024). Use of progestogens and the risk of intracranial meningioma: national case-control study. FSRH response to study: Use of progestogens and the risk of intracranial meningioma (2024) | FSRH

	• Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use (2016, amended September 2019) UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) | FSRH • Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017) FSRH Clinical Guideline: Quick Starting Contraception (April 2017) | FSRH

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Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Initial And Repeat Administration Of Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) Injection By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles Version 2.2

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Initial And Repeat Administration Of Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) Injection By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles Isles Version 2.2
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date