This Patient Group Direction (PGD) must only be used by registered healthcare 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)

Supply and/or administration of subcutaneous medroxyprogesterone acetate (SC-DMPA) injection in

Sheffield primary care services

Version Number 2.0

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)

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

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 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, General Training Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Sim Sesane	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Consultant
Alison Crompton	Community pharmacist
Andrea Smith	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 (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

The PGD template is not legally valid until it has had the relevant organisational approval - see below.

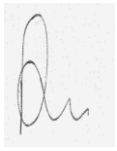
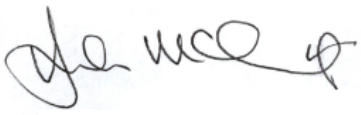
ORGANISATIONAL AUTHORISATIONS

Authorisation is limited to those registered healthcare professionals listed in Appendix A.

Any practitioner intending to work under the PGD must be individually authorised by their / the designated manager, under the current version of this PGD before working according to it (see Appendix A). Each registered healthcare professional is professionally accountable for ensuring they have undergone appropriate family planning training and are approved as competent to administer/supply depo medroxyprogesterone acetate 104mg/0.65ml (e.g. Sayana Press®) by subcutaneous injection in accordance with the following patient group direction.

The registered healthcare professional must act within their code of professional conduct at all times.

The PGD template has been reviewed, adapted to meet local requirements and authorised by:

Name	Job title and organisation	Signature	Date
Dr David Warwicker	Medical Advisor to Medicines Optimisation Team NHS South Yorkshire ICB		22nd May 2023
Emily Parsons	Medicines Governance Pharmacist (Sheffield) NHS South Yorkshire ICB		22nd May 2023
Alun Windle	Chief Nurse (Sheffield) NHS South Yorkshire ICB		31st May 2023
Person signing on behalf of authorising body: **Dr A McGinty**	Chair of Sheffield APG and Clinical director NHS South Yorkshire ICB		31st May 2023

Note: this PGD only applies to SC-DMPA (e.g. Sayana Press®) supply and/or administration.

See separate PGD for administration of intramuscular medroxyprogesterone acetate (IM DMPA) injection (e.g. Depo-Provera®)

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation. 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. Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme 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 in contraceptive administration or complete a self-declaration of competence for contraception administration. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
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 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.
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). **Gastro-intestinal conditions** • Severe decompensated cirrhosis. **Interacting medicines** – see current British National Formulary (BNF) or individual product SPC
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. • 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. • Individuals of any age with significant lifestyle and/or medical risk factors for osteoporosis, other methods of

	contraception should be considered prior to use of SC-DPMA – SC-DMPA may be considered if all alternative contraceptive options are unsuitable or unacceptable. Significant risk factors for osteoporosis include: ○ Alcohol abuse and/or tobacco use ○ Chronic use of drugs that can reduce bone mass, e.g. anticonvulsants or corticosteroids ○ Low body mass index or eating disorder, e.g. anorexia nervosa or bulimia ○ Previous low trauma fracture ○ Family history of osteoporosis • **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 https://products.mhra.gov.uk/substance/?substance=MEDROXYPROGESTERONE%20ACETATE 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 under this PGD the healthcare professional must only use a pre filled syringe from stock 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 (Note: Sayana Press® is licensed for use at 13 weeks +/- 7 days): • 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. Refer to FSRH guidance (e.g. Progestogen-only Injectable Contraception Guideline - Table 4). • 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 after last unprotected sexual intercourse (UPSI) 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 after last UPSI 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 after last UPSI 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 (e.g. Progestogen-only Injectable Contraception Guideline - Table 4) 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 FSRH guidelines.(e.g. Switching or Starting Methods of Contraception and Progestogen-only Injectable Contraception Guideline - Table 2 and Table 3)
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 - SC-DMPA may be considered if all alternative contraceptive options are unsuitable or unacceptable. Significant risk factors for osteoporosis include: • Alcohol abuse and/or tobacco use • Chronic use of drugs that can reduce bone mass, e.g. anticonvulsants or corticosteroids • Low body mass index or eating disorder, e.g. anorexia nervosa or bulimia • Previous low trauma fracture • Family history of osteoporosis **If no risks are identified then it is safe to continue SC-DMPA for longer than 2 years.**

	Note: local guidance recommends 'In women who wish to use DMPA long-term, a bone density measurement after five years may be helpful to inform longer-term decisions.'

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).
	  ○ Medication will be supplied in manufacturers original pack containing a patient information leaflet
	  ○ Patient name, date, dose and name of provider organisation will be added at the time of supply

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, the BNF and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception 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 and BNF 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 • Possible weak association between current use of DMPA and breast cancer – any increased risk is likely to be small and reduce with time after stopping. • Weak association between cervical cancer and use of DMPA - any increased risk is likely to be small and reduce with time after stopping.
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 • 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. • For patients wishing to self-administer: ○ 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.
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 • Return for review annually.
Records	**Record** the following, unless already recorded in patient 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
	• Batch number and expiry date of administered and/or supplied doses
	• Advice given, including advice given if excluded or declines treatment
	• 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
	• For patients wishing to self-administer:
	  ○ 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
	
	• Recorded that supply/administration is via Patient Group Direction (PGD)
	  ○ SNOMED code: *Administration of medication under patient group direction*
	
	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.

4. Key references

Key references (accessed October 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 Guideline: (December 2014, amended October 2020) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-injectables-dec-2014/ • FSRH CEU Statement: Self-Administration of Sayana Press® (September 2015) https://www.fsrh.org/standards-and-guidance/documents/ceustatementsayanaselfadmin/ • Faculty of Sexual and Reproductive Health Drug Interactions

	with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use (2016, amended September 2019) https://www.fsrh.org/documents/ukmec-2016/ • Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/

Appendix A – Registered health professional authorisation sheet

SC medroxyprogesterone acetate (DMPA) injection PGD Version 2.0
Valid from: 1st June 2023 Expiry: 30th April 2026

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional
By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **(Name of organisation)**_____ **for the above named health care professionals who have signed the PGD to work under it.**			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD. You do not need to return signed forms to the ICB but GP practices must ensure that appropriate organisational records are kept of the healthcare professionals authorised to work under the PGD. You may wish to retain a copy in the individual's personal file.