NHS
South Yorkshire
Integrated Care Board

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

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

Version Number 3.1

Change history

Version and Date	Change details
Version 1 May 2020	New template
Version 1.1 November 2020	Minor rewording and highlighting contents of 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 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.

Version 2.3 April 2025	Updated contraindications and cautions in line with SmPC changes.
Version 3.0 January 2026	Planned end of life review. Reflects changes in UKMEC (2025). Updated reference from FSRH to CoSRH. Minor rewording to align the RH PGDs content, and update terminology. Update SLWG and references.
Version 3.1 July 2026	Progestogen-containing contraceptives and risk of meningioma added to Criteria for Exclusion and Further Advice to be Given to Individual reflecting CoSRH statement July 2026. Wording on meningioma aligned across reproductive health PGDs. References updated.

PGD development group

Date PGD template comes into effect:	1st May 2026
Review date:	1st November 2028
Expiry date:	30th April 2029

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 College of Sexual and Reproductive Healthcare (CoSRH) in January 2026.

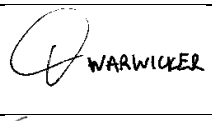
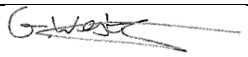
Note the working group and approving organisation(s) agreement to the content only applies to the national template and does not extend to any local adaptations made to any of the content which are solely the responsibility of the organisation authorising the PGD. The most up to date version of the template is available from the SPS national PGD, protocol and written instructions templates webpage.

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

Name or Role	Position
Alison Crompton	Community pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Carmel Lloyd	Royal College of Midwives (RCM)
Dr Cindy Farmer	Senior Vice President, Professional Learning and Development, College of Sexual and Reproductive Healthcare (CoSRH)
Clare Livingstone	Royal College of Midwives (RCM)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Heather Randle	Royal College of Nursing
Julia Hogan	Clinical Nurse Specialist
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Lisa Knight	Community Health Services pharmacist
Michelle Jenkins	Clinical Nurse Specialist Sexual Health Blackpool Teaching Hospitals, and member of Courses and CPD Committee, College of Sexual and Reproductive Healthcare (CoSRH)
Portia Jackson	Deputy Chief Pharmacist and Lead for iCaSH East of England Community Health and Care NHS Trust
Rachel Logan	Senior Pharmacist, BPAS
Tanya Lane	CoSRH Registered Trainer MSI Reproductive Choices
Jo Jenkins	Associate Director Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service

Name or Role	Position
Kieran Reynolds	Advanced Specialist Pharmacist, Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service
Rosie Furner (Working Group Co-Ordinator)	Advanced Specialist Pharmacist, Medicines Governance, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Out of Hospital Care Lead, Medicines Use and Safety, Specialist Pharmacy Service

Organisational authorisations

Name	Job title and organisation	Signature	Date
David Warwicker (Senior doctor)	Medical Lead for Medicines Optimisation, SY ICB		29/07/2026
Greg Westley (Pharmacist)	Medicines Safety Officer, South Yorkshire ICB		29/07/2026
Jayne Sivakumar **Senior representative of professional group using the PGD**	Deputy Chief Nurse, South Yorkshire ICB		29/07/2026
Alex Molyneux **Person signing on behalf of the authorising body as defined by NICE**	Chief Pharmacy Officer, South Yorkshire ICB		30/07/2026

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®)

Characteristics of staff

The decision to administer any medicine rests with the individual registered practitioner who must abide by the PGD and any associated organisation policies.

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional (HCP) listed in The Human Medicines Regulation 2012, Schedule 16 Part 4 legislation as able to practice under Patient Group Directions.
Initial training	The registered HCP authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients 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 CoSRH, 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 training and is up to date with safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	Registered healthcare professionals (HCPs) operating under this PGD must be assessed as competent (see Appendix A) or complete an appropriate self-declaration of competence for contraception supply Registered HCPs 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	Registered HCPs operating under this PGD are personally responsible for ensuring they remain up to date with the use of the medicine included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising staff to act under the PGD and further training provided as required. Organisational PGD and/or medication training as required by employing organisation

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 exclusion. • Known hypersensitivity to an active ingredient or to any constituent of the product – see the individual Summary of Product Characteristics which can be accessed on the EMC website • Unexplained vaginal bleeding suspicious of a serious medical condition, present before commencing the method • Acute porphyria • Metabolic bone disease • Post-partum (0 to <6 weeks) with other risk factors for venous thromboembolism (VTE) • Major surgery (initiation) NB: Major surgery includes major elective surgery (>30 minutes' duration) and all surgery on the legs, or surgery which involves prolonged immobilisation of a lower limb. • Known thrombogenic mutations (e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies) • Known chronic kidney disease (CKD) (all stages) • Positive antiphospholipid antibodies **Cardiovascular disease** • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic attack. • Individuals with multiple risk factors (defined as more than one risk factor) for cardio-vascular

	disease (such as smoking, diabetes, hypertension, obesity (BMI>30kg/m^2) and dyslipidaemias) • Hypertension with vascular disease. • Active thromboembolic disease • History of VTE or current VTE (on anticoagulants) • Individuals with multiple risk factors (defined as more than one risk factor) for VTE are excluded. Clinical judgement should be applied and advice from a prescriber sought. Examples of VTE risk factors include (but not exclusively) ○ family history of VTE, ○ immobility, ○ BMI> 35kg/m^2, ○ superficial VTE, ○ ovarian and endometrial cancer, ○ inflammatory bowel disease, ○ sickle cell disease **Cancers** • Currently being treated or completed treatment for breast cancer • Malignant liver tumour (hepatocellular carcinoma) • Individuals with a current meningioma or a history of meningioma **Gastro-intestinal Conditions** • Severe hepatic impairment. • Known severe (decompensated) cirrhosis • Benign liver tumour (hepatocellular adenoma) **Interacting medicines –** see current British National Formulary (BNF) or individual product SmPC which is available on the EMC website
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 medical/independent non-medical 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: o Alcohol abuse and/or tobacco use o Chronic use of drugs that can reduce bone mass, e.g. anticonvulsants or corticosteroids o Low body mass index or eating disorder, e.g. anorexia nervosa or bulimia o Previous low trauma fracture o Family history of osteoporosis o CKD • Medication should not be re-administered pending examination if there is a sudden partial or complete loss of vision or if there is a sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, medication should not be re-administered. • **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 and implant. If a LARC method is unacceptable/unsuitable and SC-DMPA is chosen then an additional barrier method of contraception is advised.** See **CoSRH statement: Contraception for women using known teratogenic drugs (Feb 2018) FSRH**.
Actions 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 declining treatment 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.

Description of treatment

Name, form and strength of medicine	• 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 • Further brand information including full details of adverse effects and interactions is available in the individual SmPC which can be accessed on the EMC website or the MHRA website
Legal category	POM
Route or method 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 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 given by College of Sexual and Reproductive Healthcare (CoSRH) is used for guidance in this PGD and may vary from the

	Summary of Product Characteristics (SmPC) which can be accessed on the EMC website This PGD includes inclusion criteria and dosage regimen which are outside the market authorisation for many of the available products but which are included within CoSRH guidance: • Supply and/or 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/or administration after five days postpartum if not breast-feeding/before six weeks postpartum if breast-feeding. CoSRH guidance supports the use of SC-DMPA any time after childbirth for both breastfeeding and non-breastfeeding individuals (providing risk factors for VTE allow). 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 drugs 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 drug 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 required no sooner than 3 weeks after most recent UPSI. • In line with CoSRH 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 required no sooner than 3 weeks after most recent UPSI. • Can be started any time after childbirth. If started after 21 days additional barrier method / abstinence required for 7 days. • 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, the injection may be administered/supplied - the professional administering the injection should refer to FSRH current guidelines- Progesterone only injectables 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 CoSRH - Switching or Starting Methods of Contraception (log in required) and CoSRH Clinical Guideline: Contraception after Pregnancy
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).
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 • CKD **If no risks are identified, then it is safe to continue SC DMPA for longer than 2 years until the age of 50.**
Storage	Medicines must be stored securely according to national guidelines and in accordance with the Summary of Product Characteristics (SmPC) which can be accessed on the EMC website
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 included in the Summary of Product Characteristics (SmPC) which can be accessed on the EMC website or the BNF Refer also to 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 and management of adverse reactions	A detailed list of adverse reactions is included in the Summary of Product Characteristics (SmPC) which can be accessed on the EMC website or the 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, indurations, scarring and atrophy at injection site, injection site discolouration • Disturbance of bleeding patterns • Changes in mood • Weight change • Loss of libido • A delay of up to 1 year in the return of fertility after discontinuation of IM or SC DMPA. • Association with a small loss of bone mineral density which is recovered after discontinuation of the injection
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 procedures for adverse reactions	• Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the MHRA's Yellow Card Scheme and follow organisation policy. • Record all adverse drug reactions (ADRs) in the individual's clinical record. • Report via organisation incident policy • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Written information and further advice to be given to individual or carer	• Provide manufacturer's information leaflet (PIL) provided within 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. • Advise there may be a delay of up to 1 year in the return of fertility after discontinuation of IM or SC DMPA. • 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 use of some progestogen-containing hormonal contraception and a small increased risk of intracranial meningioma requiring surgery
Advice / Follow-up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should seek further advice if they have any concerns. • Return for review annually.
Records to be kept	• The consent of the individual and/or o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines.

	○ If individual under 16 years of age and not competent, record action taken ○ If individual over 16 years of age and not competent, record action taken • If individual not treated under PGD record action taken • Name of individual, address, date of birth • GP contact details where available/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 • Dose supplied/administered, and if administered record site of administration • 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 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. All records should be kept in line with NHS England Records Management Code of Practice. This includes individual data, master copies of the PGD and lists of authorised practitioners.

Key references (accessed December 2025, and July 2026)

- Electronic Medicines Compendium
- Current edition of British National Formulary
- NICE Medicines practice guideline MPG2 - Patient Group Directions - Last Updated 27 March 2017
- College of Sexual and Reproductive Healthcare Clinical Guidance: Progestogen-only Injectable Contraception (December 2014, amended July 2023)
- CoSRH CEU Statement: Self-Administration of Sayana Press® (September 2015)
- College of Sexual and Reproductive Healthcare Drug Interactions with Hormonal Contraception – May 2022
- College of Sexual and Reproductive Healthcare Switching or Starting Methods of Contraception (amended May 2025) (log in required)
- College of Sexual and Reproductive Healthcare CEU Statement: Response to new study by Roland et al (2024). Use of progestogens and the risk of intracranial meningioma: national case-control study.
- College of Sexual and Reproductive Healthcare CEU Statement: Response to new study by Lundstrøm et al. (2026). Contraceptive Progestogens and Incident Meningioma
- College of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use (2025)
- College of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017)

Appendix A - Registered health professional authorisation sheet

PGD Name: SC medroxyprogesterone acetate (DMPA) injection

Version: 3.1

Valid from: 29/07/2026

Expiry: 30/04/2029

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 and agree with the following statement:

'I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.'

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

It is the responsibility of each professional to practice only within the bounds of their own competence and 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 _____ (Insert name of organization) for the above-named health care professionals who have signed the PGD to work under it

Name		Designation	Signature	D

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.