Patient Group Direction: For the administration of intramuscular Medroxyprogesterone Acetate (IM-DMPA) 150mg/ml injection as Depo Provera® by Registered Nurses working in GP practices across NHS Somerset ICB (PGD Number: 1 Version 6.0)

Staff involved in the development of this PGD:

	Name	Signature	Date
Doctor	Dr Andrew Tresidder NHS Somerset Medicines Programme Board Chair	Andrew Tresidder	1.4.2025
Pharmacist	Hels Bennett Medicines Manager, NHS Somerset ICB	H.M. Bennett	26.03.2025

Lead Nurse involved in the development of the original Somerset CCG Document: Karen Maddison, Nurse Practitioner, Harley House Surgery.
Name of original author: Dr R Hobbs, Clinical Director, CASH service, Somerset Partnership Trust

Authorised for use across NHS Somerset ICB Practices by:

Shelagh Meldrum, Chief Nursing Officer for NHS Somerset ICB (Acting as Clinical Governance Lead)

Signed: ..... Date: 4.4.25

Valid from: 1 June 2025
Expiry Date: 31 May 2027

TO BE COMPLETED BY GP SURGERY:

I, Doctor ....., as clinical lead for ..... surgery, have read and approved this PGD for use by appropriate registered nurses employed at my surgery. I understand that I am responsible for ensuring that nursing staff have adequate training to ensure that MEDROXYPROGESTERONE ACETATE INJECTION as Depo Provera® is administered to patients in strict accordance with this PGD.

Signed..... Date:.....

Patient Group Direction: For the administration of intramuscular Medroxyprogesterone Acetate (IM-DMPA) 150mg/ml injection as Depo Provera® by Registered Nurses working in GP practices across NHS Somerset ICB (PGD Number: 1 Version 6.0)

Date of Implementation: 1 June 2025
Expiry Date: 31 May 2027

The Registered Nurses named below are authorised to administer intramuscular Medroxyprogesterone Acetate (IM-DMPA) 150mg/ml injection as Depo Provera® as specified under this Patient Group Direction, being employees of …… …… (INSERT PRACTICE NAME)

In signing this document, I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD.
- I agree to administer the above preparation in accordance with this PGD

NAME *(please print)*	TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

- **Complete additional pages as necessary.**
- **Retain original signed pages (1) and (2) with authorising manager**

Patient Group Direction: For the administration of intramuscular Medroxyprogesterone Acetate (IM-DMPA) 150mg/ml injection as Depo Provera® by Registered Nurses working in GP practices across NHS Somerset ICB (PGD Number: 1 Version 6.0)

N.B. You must be authorised by name, under the current version of this PGD before you attempt to work in accordance with it.

1. Clinical Condition

Definition of condition / situation	Contraception
Criteria for inclusion	• Individual aged 13 years to 50 years presenting for long term progestogen-only contraception. • Informed consent given. **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 the available products but which are included within FSRH guidance: o Can be administered after day 5 of a cycle o Can be administered between 10-14 weeks. Refer to FSRH guidance for administration after 14 weeks. o Administration after five days postpartum if not breast feeding/before six weeks postpartum if breast feeding. FSRH guidance supports the use of IM DMPA any time after childbirth for both breastfeeding and non-breastfeeding individuals. 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.
Exclusion criteria	• Informed consent not given • Before menarche • Temporary residents. These patients should be evaluated by a GP or appropriately trained non-medical prescriber. • Individuals under 13 years of age • 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

Exclusion criteria (continued)	• 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 • 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 • Malignant liver tumour (hepatocellular carcinoma) • History / diagnosis of meningioma. **Gastro-intestinal conditions** • Severe decompensated cirrhosis • Benign liver tumour (hepatocellular adenoma).
Caution including relevant actions to be taken	• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented • 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 IM DMPA first line for contraception because of its effect on bone mineral density. IM 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 IM DPMA – IM 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

Caution including relevant actions to be taken (continued)	• For FSRH advice on switching from other methods of contraception to progestogen-only injectable contraception see https://www.fsrh.org/Public/Documents/fsrh-ceu-guidance-progestogen-only-injectables.aspx • Assessment of patients attending for progestogen-only injectable contraception should include a sexual history and sexually transmitted infection (STI) risk assessment. Where appropriate, an STI screen should be offered, and should be advised if there has been a risk of STI exposure or symptoms such as altered bleeding. • Health professionals should check that patients requesting IM DMPA are up-to-date with cervical cytology screening and, if relevant, have completed the HPV vaccination programme. • Young people <18 years – consider child-protection issues. • Vulnerable adults – consider safeguarding issues. • Since loss of bone mineral density (BMD) may occur in patients of all ages who use Depo-Provera injection long-term, a risk/benefit assessment, which also takes into consideration the decrease in BMD that occurs during pregnancy and/or lactation, should be considered before giving the injection of Depo-Provera. • 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. • Post-partum - Depo-Provera injection should be used with caution in the puerperium. Patients who are considering use of the product immediately following delivery or termination should be advised that the risk of heavy or prolonged bleeding may be increased. • Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Individuals should be advised to contact their GP in case of mood changes and depressive symptoms, including shortly after initiating the treatment. **Breastfeeding** • Potential breastfeeding risks associated with early (<6 weeks) postpartum medroxyprogesterone use should be discussed as part of a shared decision-making process to allow for fully informed consent. **Drug Interactions** ○ All concomitant medications should be checked for interactions. ○ The efficacy of IM DMPA is **not** reduced with concurrent use of enzyme-inducing drugs. ○ A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website http://www.medicines.org.ukthe BNF http://www.bnf.org and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022)

	○ If ulipristal acetate emergency hormonal contraception recently taken - hormonal contraception should not be quick started until 5 days after to avoid failure of ulipristal. ○ Refer to a prescriber if any concern of a clinically significant drug interaction. • **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 IM-DMPA is chosen then an additional barrier method of contraception is advised. See FSRH advice.**
Action if excluded	• Explain the reasons for exclusion to the individual and document in the consultation record • Patients who are excluded from the PGD will require specific consideration and should be referred to a GP, appropriately trained non-medical prescriber, Somerset Wide Integrated Sexual Health (SWISH) doctor, or other suitable health service provider as appropriate. • Document action taken
Action if patient refuses medication	• Clearly document the decision in the patient's notes and consider referral to a GP or a SWISH doctor as appropriate. • Provide advice on alternative methods of contraception as appropriate.

2. Characteristics of Staff

Professional qualification to be held by staff working under this Patient Group Direction	NMC Registered Nurses

Additional requirements	• 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 patients ensuring safe provision of the medicines listed in accordance with local policy. • Recommended 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 • Has undertaken anaphylaxis and resuscitation training. • Immediate access to adrenaline / epinephrine 1:1000. • Knowledge of NICE Guidance on PGDs: http://www.nice.org.uk/Guidance/MPG2 • Knowledge of RCN and RPS Professional Guidance on the Administration of Medicines in Healthcare settings • Knowledge of NMC Code of conduct: The Code http://www.nmc-uk.org/Publications/Standards/The-code/Introduction/ • Has undertaken locally required training in child and adult safeguarding, including updates. • Familiarity with current FSRH guidance on progestogen-only injectables and 'quick starting' contraception including guidance on quick starting after ulipristal acetate. Must also be aware of any relevant updates to guidance. • Maintenance of own level of competence in line with continued professional development requirements • Individuals operating under this PGD must be assessed as competent 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

	• Individuals operating under this PGD are personally responsible for ensuring 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. **The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.**

3. Description of Treatment

Name of Medicine	Medroxyprogesterone Acetate 150 mg/ml Sterile Suspension for Injection (Depo Provera®)
Legal Class	POM (Prescription Only Medicine)
Storage	• Store in a locked cupboard • Store in original packaging • Do NOT store above +25°C. • Do NOT refrigerate or freeze
Method or route of administration	Intramuscular injection (IM) **Advice for administration:** • Follow manufacturers' guidance for administration • Shake the syringe/vial vigorously before administration • Deep intramuscular injection into the gluteal (preferred) or deltoid muscle • Ensure that the full contents of the syringe/vial is administered • Do not massage the site after the administration of the injection.
Dose to be used (including criteria for use of differing doses)	150mg (1 ml)
Frequency	• Single IM injection (150mg/1ml) on day 1-5 of the menstrual cycle with no need for additional protection • IM 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 UPSI.

Frequency (continued)	• When starting or restarting IM 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. • IM 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, IM 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 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.
Total dose and number of times drug to be given	• Single dose is to be administered per episode of care. • Duration of treatment: for as long as individual requires IM 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 every 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 IM DPMA – IM 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 IM DMPA for longer than 2 years until the age of 50.**

Advice and information to patient/carer including follow-up

- The Medroxyprogesterone Acetate (Depo-Provera®) patient information leaflet (PIL) must have been supplied to the patient prior to administration of the contraceptive. Patients must be given enough time to re-read the PIL if they wish and the chance to ask relevant questions prior to drug administration.

- Explain mode of action, side effects, risks and benefits of the medicine

- Advise the patient on possible side effects:

The following possible side effects are commonly reported with IM DMPA (but may not reflect all reported side effects):

- Headache, dizziness
- Disturbance of bleeding patterns
- Changes in mood
- Weight change
- Breast tenderness
- Loss of libido
- Abdominal discomfort or distension, nausea
- Alopecia, acne, rash
- Genitourinary tract infection
- 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.

- Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Individuals should be advised to contact their GP in case of mood changes and depressive symptoms, including shortly after initiating the treatment.

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

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 and where appropriate, report via organisation incident policy.

Advice and information to patient/carer including follow-up (continued)

- The injection site should not be rubbed after the injection is given as this leads to increased drug distribution.
- Patients should be counselled that there could be a delay in return to full fertility (up to 1 year) following use of the method, regardless of the duration of use.
- Patients who discontinue their progestogen-only injectable and who do not wish to conceive should be advised to start another contraceptive method before or at the time of their next scheduled injection even if amenorrhoeic.
- Patients who satisfy the criteria for supply by PGD must be counselled about compliance with the repeat administration schedule.
- Patients requesting the progestogen-only injectable should be informed that IM DMPA injection does not protect against sexually transmitted infections and that the consistent and correct use of condoms provides an effective means of protecting against HIV and other STIs
- Patients switching to IM DMPA from another method of contraception should be provided with advice on whether and how long additional contraceptive precautions are needed. This information can be found in FSRH Clinical Guidance on Progestogen-only Injectable Contraception : FSRH Clinical Guideline: Progestogen-only Injectables (December 2014, amended July 2023) | FSRH
- If the first injection is administered after day 5 of the menstrual cycle, or more than 14 weeks has elapsed since the last injection, additional contraception will be required for 7 days.
- Advise on the date that the next injection is due and ask the patient to return on this date, or sooner if they experience any adverse reactions or intolerable side effects.
- 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 if appropriate.

- 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.

Specify method of recording supply /administration including audit trail	Adverse drug reactions must be clearly documented and, where appropriate, reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card scheme at http://yellowcard.mhra.gov.uk and also follow the local incident reporting procedure.
	
	The following will be recorded in the patient's clinical records:
	• Consent given, and
	  ○ 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
	• The name of the medicine
	• The dose administered
	• The batch number and expiry date
	• The route and site of administration
	• Date of administration
	• The signature and name of the person administering the medication (for computer records, health professionals must have an individual identifier to enable an audit trail)
	• Height, weight and BMI
	• Blood pressure
	• Date of last injection and elapsed time since last injection
	• Elapsed time of continuous use and date next review by GP or non-medical prescriber should take place
	• LMP & Bleeding pattern
	• Any problems
	• Advice given, including advice given if excluded or declines treatment
	• Individual has been advised on the date(s) for 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 administration outside the terms of the product marketing authorisation
	• Record that administration is via Patient Group Direction (PGD)
	
	It is a legal requirement to keep auditable records of administration and supply of medication via a PGD.
	
	All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners.
	
	All records should be clear, legible and contemporaneous and made in appropriate patient notes.

References used in the development of this PGD:	• BNF online • Summary of Product Characteristics: https://www.medicines.org.uk/emc/product/6721/smpc • 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) Available at: Progestogen-only Injectables FSRH • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) FSRH • Faculty of Sexual and Reproductive Health CEU Statement: FSRH response to study: Use of progestogens and the risk of intracranial meningioma (2024) FSRH • Faculty of Sexual and Reproductive Health Clinical Guidance on Quick Starting Contraception (April 2017): FSRH Clinical Guideline: Quick Starting Contraception (April 2017) FSRH • Faculty of Sexual and Reproductive Health Clinical Guidance on Emergency Contraception (March 2017, amended December 2020): https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use (2016, amended September 2019) • IM DMPA National PGD template v2.2 Nov 2024 Medroxyprogesterone acetate (DMPA) IM injection for contraception – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 1st June 2025 and expires 31st May 2027

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.1	19/12/14	Somerset Partnership PGD for Depo Provera put into NHS Somerset CCG template and reviewed in line with current SPC, BNF and FSRH guidance	Catherine Henley, Medicines Manager, Somerset CCG
0.2	5/12/15	Discussion with Dr Ruth Wells and Karen Maddison amended with additional safety nets	Catherine Henley, Medicines Manager, Somerset CCG
0.3	8/1/15	Minor amendments in response to final comments from Dr Ruth Wells and Karen Maddison	Catherine Henley, Medicines Manager, Somerset CCG

Version	Date	Brief Summary of Change	Owner's Name
1.0	14/1/15	Final version after minor corrections following PAMM meeting	Catherine Henley, Medicines Manager, Somerset CCG
1.1	24/3/17	Catherine Henley- review of version 1.0 against current SPC, BNF and FSRH guidance	Catherine Henley, Medicines Manager, Somerset CCG
2.0	19/4/17	Document reviewed by GP members at Somerset PAMM meeting and content agreed	Catherine Henley, Medicines Manager, Somerset CCG
2.1	30/4/19	Catherine Henley- review of version 2.0 and amendment against current SPC, BNF and FSRH guidance	Catherine Henley, Medicines Manager, Somerset CCG
3.0	8/5/19	Document reviewed and approved by GP members at Somerset PAMM meeting	Catherine Henley, Medicines Manager, Somerset CCG
4.0	06.05.21	PGD reviewed & updated against current SPC, BNF & FSRH guidance. Additional recording requirements added. Minor formatting changes. CCG logo updated.	Hels Bennett, Medicines Manager, Somerset CCG
4.1	13.05.21	Final version after minor amendments following comments at Somerset PAMM	Hels Bennett, Medicines Manager, Somerset CCG
5.0	06.04.23	PGD reviewed & updated. Minor formatting changes. Cautions added relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.	Hels Bennett, Medicines Manager, NHS Somerset ICB
5.1	25.04.23	Further information added regarding Lactational amenorrhea method of contraception (LAM). Caution added re: consideration of bone mineral density (BMD) risk/benefit assessment which also takes into consideration the decrease in BMD that occurs during pregnancy and/or lactation. Further formatting changes including inclusive language. PGD approved at Somerset MPB.	Hels Bennett, Medicines Manager, NHS Somerset ICB
6.0	29.01.25	Planned review and update. PGD updated using national IM-DMPA PGD template. Cautions added; to discuss breastfeeding risks associated with early (<6 weeks) postpartum use, use of recent ulipristal EHC, risk of depression with hormonal contraception. PGD approved at NHS Somerset MPB March 2025.	Hels Bennett, Medicines Manager, NHS Somerset ICB