

Patient Group Direction: The Administration of Medroxyprogesterone Acetate 150mg/ml injection as Depo Provera[®] by Registered Nurses working in GP practices across NHS Somerset CCG (PGD Number: 1 Version 4.1)

Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Dr Andrew Tresidder Somerset CCG Prescribing and Medicines Management Group Chair		19.5.21
Pharmacist	Hels Bennett Medicines Manager, Somerset CCG		13.05.2021

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****Expiry Date: 31 May 2023****Authorised for use across NHS Somerset CCG Practices by:****Val Janson, Director of Quality and Nursing for NHS Somerset CCG (Acting as Clinical Governance Lead)**

Signed: Date: 19/05/2021

Date of Implementation: 1 June 2021

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:.....

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Expiry Date: 31 May 2023

The Registered Nurses named below are authorised to administer Medroxyprogesterone Acetate 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/supply the above preparations in accordance with this PGD

NAME <i>(please print)</i>	TITLE	SIGNATURE	AUTHORISING MANAGER <i>(please print)</i>	MANAGER'S SIGNATURE	DATE

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

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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

- First administration of intramuscular medroxyprogesterone acetate 150mg/ml injection (Depo-Provera[®]) (IM DMPA) to females aged 13 years to 50 years requiring long-term progestogen-only contraception
- Repeat administration of Medroxyprogesterone acetate 150mg/ml injection (Depo-Provera[®]) (IM DMPA) to females aged 13 years to 50 years requiring long-term progestogen-only contraception.

N.B. If the first injection is given by someone other than a doctor or non-medical prescriber then an assessment by a doctor or appropriately trained non-medical prescriber must take place prior to/or with second injection.

Patients having repeat IM DMPA under this PGD must have been re-evaluated by a GP or, an appropriately trained non-medical prescriber at the practice within the last 2 years.

Criteria for inclusion

For all patients (first and repeat injections):

- Female patients aged between 13 years to 50 years of age.
- Valid informed consent by the individual or by the person with parental responsibility
- If the individual is under 16 years and consenting to treatment, the nurse must ensure that they are “Fraser Competent”
- If under 18 years of age, in accordance with the recommendations of the Faculty of Sexual and Reproductive Healthcare (FSRH), all contraceptive options have been discussed and considered unsuitable or unacceptable.
- Breastfeeding women who are more than 6 weeks post-partum.

For repeat injections:

- The patient’s need for IM DPMA has been reviewed by a doctor, or appropriately trained non-medical prescriber at the practice prior to the first or second injection.
- The need for IM DPMA has been re-evaluated by a doctor, or appropriately trained non-medical prescriber at the practice within 2 years of the first injection (if this method has been used continuously)
- between 10 weeks, 0 days and 11 weeks 6 days has elapsed since the last injection and there is a good reason why the patient isn’t able to attend for repeat injection at the normal time.*
- between 12 weeks, zero days and 14 weeks, zero days have elapsed since the last injection**

- If more than 14 weeks since last injection but **NO** episodes of unprotected sexual intercourse (UPSI) since the injection ceased to provide protection. If the injection is administered, advise the patient to use additional contraception for the next 7 days.
- No adverse drug reactions to previous injection have occurred.

* Repeat doses administered before (12 weeks and 0 days) are given outside the product license but current FSRH guidance states that, if necessary, an early repeat of IM DMPA can be given from 10 weeks after the last injection.

** Repeat doses given after 89 days (12 weeks and 5 days) is outside the product license but current FSRH guidance states that women attending late (up to 14 weeks since the last injection) for repeat IM DPMA may be given the injection without the need for additional contraception.

N.B. Every effort should be made to adhere to the 12 week administration schedule. If the repeat IM DMPA injection is being considered outside the interval stated in the Summary of Product Characteristics, the women should be advised of, and consent to unlicensed use, prior to administration.

Exclusion criteria

NB: excluded patients should be referred back to a doctor to consider whether further action is required.

For all women considering IM DMPA injection:

- Who are temporary residents. These women should be evaluated by a GP or appropriately trained non-medical prescriber.
- Where valid consent has **NOT** been given.
- History of true anaphylactic reaction to Depo-Provera® or any other progestogen.
- Known hypersensitivity to any component of Depo-Provera injection® (see Summary of Product Characteristics (SPC) for full list of excipients).
- Young people under 13 years – child protection issues must be addressed.
- Women over 50 years of age.
- Young People aged between 13 and 16 who do not meet the criteria set out in the “Fraser Ruling”. Child protection issues must be addressed.
- Women aged over 16 years where mental capacity to provide informed consent is in doubt.
- Before menarche
- Known or suspected pregnancy.
- Where a nurse cannot be ‘reasonably certain’ that the woman is not already pregnant as per FSRH criteria for excluding pregnancy. The FSRH state that health professionals can be ‘reasonably certain’ that a woman is **not currently pregnant** if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:

- She has not had intercourse since the start of her last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- She has been correctly and consistently using a reliable method of contraception. (For the purposes of being reasonably certain that a woman is not currently pregnant, barrier methods of contraception can be considered reliable providing that they have been used consistently and correctly for every episode of intercourse.)
- She is within the first 5 days of the onset of a normal (natural) menstrual period.
- She is less than 21 days postpartum (non-breastfeeding women).
- She is fully breastfeeding, amenorrhoeic AND less than 6 months postpartum.
- She is within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- She has not had intercourse for >21 days AND has a negative high-sensitivity urine pregnancy test (able to detect hCG levels around 20 mIU/ml).

NB. Health professionals should also consider if a woman is **at risk of becoming pregnant** as a result of UPSI within the last 7 days

Exclusion criteria continued:

- Women requesting the progestogen-only injectable following emergency contraception (EC). These women should be offered an oral contraceptive as a temporary 'bridging' method. If this is unacceptable, then they should be referred to a doctor or appropriately trained non-medical prescriber for review. **N.B. The effectiveness of a progestogen-containing contraceptive that is quick started immediately after administration of ulipristal acetate (UPA) might be reduced by UPA due to competition at the progesterone receptor site. Additionally, the effect of UPA in delaying ovulation might be reduced by quick-starting a progestogen-containing contraceptive. The FSRH recommend that after taking UPA for EC, a woman should not start a hormonal contraceptive method for at least 5 days. See [FSRH Guidance on Drug interactions with Hormonal Contraception](#) for further information**
- Women who are breast feeding and who are less than 6 weeks post-partum.
- Known osteoporosis.
- Women with significant lifestyle and/or medical risk factors for osteoporosis. Significant risk factors 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
- Diabetes mellitus with new complication i.e. nephropathy/ retinopathy/ neuropathy, vascular disease or non-vascular disease.
- Current/ history of ischaemic heart disease or thromboembolic disease.

- Multiple risk factors for cardiovascular disease such as older age, smoking, diabetes, hypertension and obesity.
- History of stroke, including transient ischaemic attack.
- Hypertension with vascular disease such as angina, coronary heart disease, peripheral vascular disease, hypertensive retinopathy, transient ischaemic attacks.
- Severe liver disease, cholestatic jaundice or hepatitis (viral or non-viral).
- Porphyria.
- Unexplained vaginal bleeding suspicious for serious underlying condition.
- Patients with a known or suspected hormone-dependent malignancy of breast or genital organs.
- Systemic Lupus Erythematosus (SLE).
- Women being treated with aminoglutethimide.
- Women being treated with ulipristal as this may reduce contraceptive effect of progestogens

For repeat injections-

- More than 14 weeks have elapsed since the last injection and UPSI has taken place since the injection ceased to provide protection.
- Where the woman was not assessed by a GP or suitably trained non-medical prescriber at the practice prior to administration of the first injection. These women should be re-evaluated by a doctor or appropriately trained non-medical prescriber prior to the second injection.
- Women who have used IM DMPA injection continuously for 2 years and a re-evaluation of the risks and benefits of treatment has **NOT** been carried out by a GP or suitably trained non medical prescriber at the practice. A review should be carried out by a GP or suitably trained non medial prescriber at the practice for every 2 years of continuous use.
- Development of new migraine or development of aura in patient with known migraine.
- Unacceptable weight gain since last administration of IM DMPA injection. Women who 5% of their baseline body weight in the first 6 months of use are likely to experience continued weight gain.

Caution	<ul style="list-style-type: none"> • If patient is taking any other medications consult the British National Formulary (BNF) Appendix 1 for any potential interactions and the FSRH clinical guidance on Interactions with Hormonal Contraception • FSRH advice on switching from another contraceptive to progestogen only injectable contraception must be followed (see pages 13 & 14 of guidance): http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyInjectables.pdf • Assessment of women 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 women requesting IM DMPA are up-to-date with cervical cytology screening and, if relevant, have completed the HPV vaccination programme. • Young people under the age of 18 years – consider child-protection issues. • Vulnerable adults – consider issues around protection of vulnerable adults. • Use of IM DMPA appears to be associated with weight gain, particularly in women under 18 years of age with a body mass index (BMI) ≥ 30 kg/m². • Women who gain more than 5% of their baseline body weight in the first 6 months of IM DMPA use are likely to experience continued weight gain. • 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 as per FSRH recommendations. • Depo-Provera should be used with caution in the puerperium. Women 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.
Action if excluded	<ul style="list-style-type: none"> • Further explanation to gain consent, if appropriate. • Patients who are excluded from the PGD will require specific consideration and should be referred to a GP, appropriately trained non-medical prescriber or Somerset Wide Integrated Sexual Health (SWISH) doctor, as appropriate. • Document action taken
Action if patient refuses medication	<ul style="list-style-type: none"> • 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

Registered Nurses

Additional requirements

- Has undertaken anaphylaxis and resuscitation training.
- Immediate access to adrenaline / epinephrine 1:1000.
- The healthcare professional has undertaken appropriate training to carry out clinical assessment of a patient leading to diagnosis that requires treatment according to the indications listed in this PGD.
- The healthcare professional has undertaken continuing professional development (CPD) to ensure that they understand the legal framework for the supply and administration of medicines under PGDs
- Knowledge of NICE Guidance on PGDs: <http://www.nice.org.uk/Guidance/MPG2>
- The healthcare professional must be authorised by name, under the current version of this PGD before working under it.
- The healthcare professional must be willing to be professionally accountable for this work and be working within his/her competence.
- 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/>
- The practitioner should be aware of any change to the recommendations for the medicine listed.
- Has undertaken training in child and adult safeguarding updates.
- Familiarity with current FSRH guidance on injectable progestogen contraceptives 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.

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	<ul style="list-style-type: none"> • Store in a locked cupboard • Store in original packaging • <u>Do NOT</u> store above +25°C. • <u>Do NOT</u> refrigerate or freeze
Method or route of administration	<ul style="list-style-type: none"> • Deep Intramuscular injection into the upper outer buttock • Shake the syringe / vial vigorously immediately prior to administration to ensure a uniform suspension. • Do NOT massage the injection site
Dose to be used (including criteria for use of differing doses)	150mg (1 ml)
Frequency	<p><u>First injection:</u></p> <ul style="list-style-type: none"> • Should ideally be given on days 1 to 5 of menstrual cycle. • If the <u>first injection</u> is to be administered from day 6 of the menstrual cycle onwards, a barrier method of contraception will be required for 7 days. This should ONLY be done if the nurse is reasonably certain that pregnancy can be excluded (as per FSRH guidance). <p><u>Repeat injections:</u></p> <ul style="list-style-type: none"> • Repeat injections should be given at 12 week intervals (can be extended up to 14 weeks and zero days). If more than 14 weeks have elapsed since the last injection, IM DMPA should NOT be administered if unprotected sexual intercourse has taken place since the last injection ceased to provide protection. <p>NB: Patients must be reviewed by a SWISH doctor, General Practitioner or independent nurse prescriber at least every two years.</p>
Total dose and number of times drug to be given. Details of supply (if supply made)	A single dose

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.
- 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.
- If providing the first injection under this PGD, inform the patient that they will need to be re-evaluated by a doctor/ non-medical prescriber at the practice prior to the second injection. Advise on how to make an appointment.
- When 1 year and 9 months of continuous use have elapsed since the first DPMA injection, and the woman wishes to continue, advise the patient that they need to be re-evaluated by a prescriber prior to the next injection. Arrange/ advise on how to arrange an appointment.
- Emphasise the likelihood of menstrual disturbances.
- Emphasise that the injection site should not be rubbed after the injection is given as this leads to increased drug distribution.
- Whilst there is little evidence available to demonstrate causation, a number of possible side effects such as acne, decreased libido, mood swings, headache, hot flushes and vaginitis have been reported with use of IM DMPA.
- Women 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.
- Women 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.
- Women should be made aware of possible small loss of bone mineral density – bone loss is mainly in first 2-3 years of use and then levels off. It is at least partially reversible after discontinuation of IM DMPA injection. Regular weight bearing exercise can help to strengthen bones and a healthy diet including plenty of calcium (dairy products) and vitamin D (e.g. oily fish).
- Patients who satisfy the criteria for supply by PGD must be counselled about compliance with the 12 weekly repeat administration schedule.
- Women 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
- Current evidence suggests that there is possibly a weak association between current use of IM DMPA and breast cancer. Any increased risk is likely to be small and reduce with time after stopping.
- Current evidence suggests that there is a weak association between cervical cancer and use of IM DMPA for 5 years or longer. Any increased risk appears to reduce with time after stopping and could be due to confounding factors. Women should be informed about the link between HPV and cervical cancer, and advised about strategies that reduce the risk such as condom use, smoking cessation, regular cervical screening and, where appropriate, vaccination against HPV.
- Women 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 : http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyInjectables.pdf_p13

- 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.
- Counsel patients on healthy lifestyle measures including stopping smoking.

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)
- Weight and BMI
- Height
- 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)

References used in the development of this PGD:

- [BNF online](#) accessed 06/05/2021
- Summary of Product Characteristics accessed 06/05/2021 from: <https://www.medicines.org.uk/emc/product/6721/smhc>
- Faculty of Sexual and Reproductive Health Clinical Guidance on Progestogen-only Injectable Contraception (December 2014, amended October 2020): <http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyInjectables.pdf>
- Faculty of Sexual and Reproductive Health Clinical Guidance on Quick Starting Contraception (April 2017): <http://www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf>
- Faculty of Sexual and Reproductive Health Clinical Guidance on Drug interactions with Hormonal Contraception (January 2017, last reviewed January 2019): <https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/>
- 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/>

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 1st June 2021 and expires 31st May 2023

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
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	06.05.2021	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	13.05.2021	Final version after minor amendments following comments at Somerset PAMM	Hels Bennett, Medicines Manager, Somerset CCG