PGD5117

South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY AND ADMINISTRATION OF INTRAMUSCULAR MEDROXYPROGESTERONE ACETATE (Depo Provera®)(DMPA) INJECTION

by registered nurses and midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:

Position of Signatory	Name	Signed	Date
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to administer and supply Intramuscular Medroxyprogesterone Acetate Injection to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from: 1st October 2017
Review date: Aug 2019. Expires on 31st Oct 2019
Replaces PGD4116

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to administer and supply Intramuscular Medroxyprogesterone Acetate Injection as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Qualification in contraception/sexual health (university modules/FSRH). Note- an introduction to contraception is not sufficient
3. Is competent in the assessment of individuals using Fraser guidelines
4. Has undergone regular training and updating in safeguarding children and vulnerable adults
5. The nurse should be familiar with current FSRH guidelines on Progestogen-only injectable contraception
6. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
7. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
8. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
9. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines
10. All registered nurses details and signature must be entered onto the PGD
11. Following administration a record of the date, and dose of the medicine should be recorded in the clients records

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	Medroxyprogesterone Acetate (Depo Provera®) 150 mg in 1 mL Injection (vial/pre-filled syringe)
Legal Classification	Prescription only medicine
Black Triangle?	No
Type	Injection
Storage	Supplies will be available from central stock location. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	Contraception
Inclusion Criteria	Any individual (aged 13 to 50 years of age with no safe guarding issues) presenting for contraception and who has no contraindications Patients aged 13 to 18 years of age should only be offered Depo-Provera as first line contraception once all other options have been discussed and considered unsuitable and documented For women continuing Depo-Provera for more than 2 years an individual risk assessment including discussion of benefits and potential risks should be undertaken and consideration given to alternative methods and this should be clearly documented
Exclusion Criteria	**Personal Characteristics & Reproductive History** • Known or suspected pregnancy • Known hypersensitivity to any constituent of the injection • Individuals under 16 years of age and assessed as not competent using Fraser guidelines • Individuals 16 years of age and over and assessed as not competent to consent using local safeguarding guidelines **Cardiovascular Disease** • Multiple risk factors for cardiovascular disease e.g. older age group, smoking, diabetes, hypertension and obesity • Hypertension with vascular disease • Current and history of ischaemic heart disease • Current and history of stroke/transient ischaemic attack

	• Diabetes with end organ disease **Cancers** • Current or past history of breast cancer • Benign liver tumour • Malignant liver tumour (hepatoma) **Gastro-intestinal conditions** • Severe decompensated cirrhosis **Osteoporosis** • History of Osteoporosis • Risk factor for Osteoporosis e.g. anorexia, family history, long term use of oral steroids and BMI<20kg/m **Other Conditions** • Systemic Lupus Erythematosus (SLE) with positive or unknown anti-phospholipid antibodies • Systemic Lupus Erythematosus (SLE) with severe thrombocytopenia if starting DMPA • Undiagnosed abnormal vaginal bleeding • Individual wishes to see a doctor **<u>Cautions:</u>** • Interacting medicines – see current BNF on interactions • Ensure emergency drugs and equipment, including adrenaline are available for the treatment of anaphylaxis and emergencies according to local policy • **Caution in adolescence**; guidance from the Medicines Health Regulatory Authority (MHRA) states that individuals under 18 years of age should only be offered this method of contraception if other methods are unsuitable, due to the potential effect on bone mineral density
Action if excluded or patient declines	• Refer to appropriate doctor/independent nurse prescriber • Discuss /offer alternative contraceptive method • Document all actions taken • Record the refusal in the clinical record and document all other actions • Refer to appropriate doctor/independent nurse

	prescriber where required • Discuss/offer alternative contraceptive method
Reasons for seeking further advice from doctor	• Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Intramuscular injection
Dose	• 150mg in 1mL injection (vial/pre-filled syringe) • Start on day 1-5 of the menstrual cycle with no need for additional protection • DMPA can be started at any time as quick start after day 5 if it is reasonably certain that the individual is not pregnant. Additional contraception is then required for 7 days after starting • DMPA should be repeated 12 weeks after the last injection. A repeat injection can be given up to 14 weeks after the previous dose with no additional contraceptive precautions, https://www.fsrh.org/documents/cec-ceu-guidance-injectables-dec-2014/ • If required it may be repeated as early as 10 weeks after the last injection • If it is more than 14 weeks since the last DMPA and UPSI has occurred, refer/discuss with appropriate doctor /independent nurse prescriber and exclude pregnancy For guidance on changing from one contraceptive method to another, and when to start after an abortion/miscarriage or post-partum, refer to the appropriate doctor/independent nurse prescriber/FSRH guidelines on switching methods. <u>Duration of Treatment:</u> Contraceptive cover is maintained for 14 weeks after injection
Administration Schedule	<u>Method:</u> Intramuscular • Shake the syringe/vial vigorously before administration (SPC) • Deep intramuscular injection into the gluteal

	(preferred) or deltoid muscle Do not massage the site after the administration of the injection
Warnings/Adverse Reactions	This list may not represent all reported side effects of this medicine. DMPA is well tolerated. **Common side effects** • Headache • 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 current use of DMPA and breast cancer • Weak association between cervical cancer and use of DMPA Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information.
Advice/Management of Adverse Reactions & Follow-up Action	In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk The public can report adverse effects directly to the

	MHRA via the yellow card scheme and should be encouraged to do so. <u>Advice to Individual:</u> • Provide Manufacturer's Patient Information Leaflet (PIL) Explain mode of action, side effects, and benefits of the medicine • Advise individual about need to return for repeat injection to service/GP practice • Remind individual about need for Human Papilloma Virus (HPV) vaccination and regular cervical smears, where appropriate <u>Follow Up:</u> • Individual to return to clinic if she has any concerns • Review and evaluate use of the method after two years of use as appropriate
Use in pregnancy and lactation	Not appropriate for PGD
Records	The authorised registered nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history • Any known allergy • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply or administration is by using a PGD and reference to the PGD number i.e. PGD0316 • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the terms of the product licence • The consent of the individual • If individual is under 16 years of age document competency using Fraser guidelines • If individual is 16 years of age and over not competent, record action taken

	• Record the name/brand, dose of the medication, quantity supplied and site of injection • Record batch number and expiry date according to local policy or national guidelines • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the nurse supplying or administering the medicine