NHS
York and Scarborough Teaching Hospitals
NHS Foundation Trust

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

PATIENT GROUP DIRECTION (PGD)

Administration of intramuscular (IM) medroxyprogesterone acetate (DMPA) injection in York and North Yorkshire Sexual health services including specialist clinical outreach services

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1.0 August 2020	New template
Version 1.1 November 2020	Minor rewording and highlighting of contents cautions section relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan. Acute porphyria and hypertension with vascular disease added as exclusion criteria.

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

PGD DEVELOPMENT GROUP	
Date PGD template comes into effect:	1st August 2020

Reference Number: 1.1
Valid from: March 2022
Review date: February 2023
Expiry date: July 2023

Review date	February 2023
Expiry date:	31st July 2023

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in July 2020.

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

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michael Nevill	Director of Nursing British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant Marie Stopes UK
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Pan London PGD working group
Dr Sarah Pillai	Pan London PGD working group
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
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Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
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Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

The PGD is not legally valid until it has had the relevant organisational authorisations.

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Ian Fairley - Consultant		07/06/2022
Senior pharmacist	KATE NIXON		11/8/22
Senior representative of professional group using the PGD	Wendy Billsborough Advanced Nurse Specialist		31/5/2022
Person signing on behalf of authorising body	Jennie Booth, Lead Nurse Medicines Management Stuart Parkes, Chief Pharmacist		4.8.22 15/8/22

PGDs 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 in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

- Trust PGD policy is available via on Staff Room
- An audit must be completed at renewal- see Trust PGD Policy for audit requirements

1. Characteristics of staff

The practitioner should be aware of any change to the recommendations for medroxyprogesterone acetate and current guidance from national authorities e.g. the BNF, FSRH and NICE.

It is the responsibility of the individual to keep up to date with continued professional development and to work within the limitations of their individual scope of practice

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of 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. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for contraception administration. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Contraception
Criteria for inclusion	• Individual (age from menarche to 50 years) presenting for contraception. • Consent given.
Criteria for exclusion	• 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. • Known or suspected pregnancy. • 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. • Benign liver tumour (hepatocellular adenoma). • Malignant liver tumour (hepatocellular carcinoma). **Gastro-intestinal conditions** • Severe decompensated cirrhosis. **Interacting medicines** – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk
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 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 • **Offer Long Acting Reversible Contraception (LARC) to all individuals in particular those with medical conditions for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.** • **If an individual is known to be taking a medication which is known to be harmful to pregnancy a highly effective form of contraception is recommended. Highly effective methods include the LARC methods: IUD, IUS and implant. If a LARC method is unacceptable/unsuitable and a IM-DPMA is chosen then an additional barrier method of contraception is advised. See FSRH advice.**
Action to be taken if the individual is excluded or declines treatment	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Medroxyprogesterone Acetate 150 mg in 1 mL Injection (vial/pre-filled syringe)
Legal category	POM
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.
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: • Can be administrated between 10-14 weeks. Refer to FSRH guidance for administration after 14 weeks. • 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. Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	• Single 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 if there was a risk of pregnancy • 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 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 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.
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.**
Quantity to be supplied	Single dose is to be administered per episode of care.
Storage	Medicines must be stored securely according to national guidelines.
Drug 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 www.medicines.org.uk the BNF www.bnf.org and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following possible adverse effects are commonly reported with IM DMPA (but may not reflect all reported adverse 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 There is a possible weak association between current use of IM DMPA and breast cancer and a weak association between cervical cancer and use of IM DMPA - any increased risk is likely to be small and reduce with time after stopping.
Additional facilities and supplies	• Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000)
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	• Provide patient information leaflet (PIL) provided with the original pack. • Explain mode of action, side effects, risks and benefits of the medicine • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs) • Ensure the individual has contact details of local service/sexual health services.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • Individual to seek further advice if they has any concerns.
Records	**Record:** • The consent of the individual and 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 not competent record action taken. o If individual over 16 years of age and not competent, record action taken • The consent of the individual and if individual not competent to consent record action taken • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical history, including medication and family history.

	• Any known allergies • Name of registered health professional • Name of medication supplied/administered • Date of administration • Dose administered and site of administration • Batch number and expiry date of administered • 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 • Recorded that administration is via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references (accessed March 2020)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health Clinical Guideline: (December 2014, updated April 2019) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-injectables-dec-2014/ • Faculty of Sexual and Reproductive Health CEU Guidance: Drug Interactions with Hormonal Contraception (January 2017, last reviewed 2019) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ • Faculty of Sexual and Reproductive Healthcare (2016) UK Medical Eligibility Criteria for Contraceptive Use. https://www.fsrh.org/documents/ukmec-2016/ • Faculty of Sexual and Reproductive Healthcare (2016 Clinical Guideline: Quick Starting Contraception (April 2017) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/

Appendix A - Registered health professional authorisation sheet

PGD Name - intramuscular (IM) medroxyprogesterone acetate (DMPA) injection
Valid from: March 2022 Expiry: 31st July 2023

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

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

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

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

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

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of York and Scarborough Teaching Hospitals NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

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

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD. When the expiry date is exceeded, this PGD ceases to be a legal document. Staff authorisation records must be maintained for 8 years if the PGD relates to adults only, 10 years for implants and 25 years after the expiry date if the PGD relates to children