This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practise 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 (150mg/1ml) by Registered Nurses and Midwives in BPAS Clinics.

Version Number 2.1

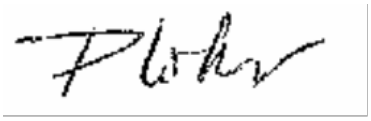
Change History	
Version and Date	Change Details
Version 1.0 August 2020	New template *Version 1.0 approved for use in BPAS 04/11/2020.*
Version 1.1 November 2020	Minor rewording and highlighting of contents cautions section relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan. Acute porphyria and hypertension with vascular disease added as exclusion criteria. *Version 1.1 approved for use in BPAS 21/12/2022. Note that clients with acute porphyria are already excluded from treatment at BPAS.*
Version 1.1 May 2023	Expiry date extended to full 3 year term from original version authorisation in November 2020.
Version 2.0 August 2023	BPAS suitability criteria added to exclusions Arrangements for referral for medical advice section added Addition of administration after day 5 of a cycle in off-label section Age limit of 50 added into duration of treatment where no risks identified Additional information entered into drug interactions section Additional information to management and reporting procedure for adverse reactions so more specific to BPAS Additional information added to records to be kept section and made more specific to BPAS.
Version 2.1 October 2023	Reworded section on cervical and breast cancer risk, in line with updated FSRH guidance. Updated references.
Version 2.1 January 2024	PGD expiry date changed from 31/10/2026 to 31/07/2026 to align with SPS PGD template expiry. No other changes to PGD content. Version number unchanged.

Valid from: 01/11/2023
Review Date: 01/05/2026
Expiry Date: 31/07/2026

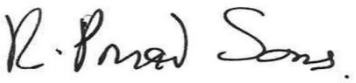
N.B. Review and update may occur prior to this period if national guidance changes or legal or clinical issues arise.

BPAS PGD Organisational Authorisations:

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

Name	Job title and organisation	Signature	Date
Vicky Garner	BPAS Consultant Midwife		16/01/2024
Patricia Lohr	BPAS Medical Director		16/01/2024
Kalpesh Thakrar	BPAS Lead Pharmacist		16/01/2024

Authorising Body:

Cheshire and Merseyside ICB	Executive Medical Director		08.11.2024

Responsible person who has approved this PGD on behalf of BPAS

Name: Lucy Moore

Position: BPAS Executive Chair

Signature: 

Date: 16/01/2024

PGD DEVELOPMENT GROUP

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 February 2023.

Name	Designation
Dr Cindy Farmer	Vice President General Training FSRH
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee FSRH
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Sim Sesane	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Heather Randle	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Consultant
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

1. Characteristics of staff authorised to use this PGD:	
Qualifications and professional registration	• NMC Registered Nurse • NMC Registered Midwife Practitioners must also fulfil the additional requirements listed below.
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. Pharmacological knowledge relating to the administration and supply of the medicine, its uses, contraindications, dosage and adverse effects Additionally, practitioners: • Must have completed appropriate training for working under a PGD for the supply / administration of medicines (see training requirements in the BPAS PGD policy) • Must be familiar with the medicine and observant to changes in the BNF and Summary of Product Characteristics (SmPC) • Must be competent in the recognition and management of adverse reactions, including anaphylaxis • Must be competent in the administration of adrenaline for anaphylaxis and have up to date Basic Life Support (BLS) skills as a minimum • Must have access to the PGD and associated online resources **The practitioner must be authorised by name, under the current version and terms of this PGD in the Approved Practitioner List before working to it.**
Competency Assessment	Practitioners working under this PGD are required to review their own competency using the NICE Competency Framework for Health Professionals using Patient Group Directions Practitioners working under this PGD must be assessed as competent or complete a self-declaration of competence to use this PGD (see appendix A). **Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.**
Ongoing training and competency	• Practitioners must complete 3-yearly PGD Theory Refresher training and competency assessment • Practitioners working under this PGD are responsible for ensuring they remain up to date with the use of the medicines and guidance included in

	the PGD, ensuring any training needs identified are addressed with further training • Practitioners must make sure they are aware of any changes to the recommendations for this medication • Practitioners must ensure they remain up to date with relevant clinical skills, management of anaphylaxis, BLS (as a minimum), with evidence of continued professional development • Practitioners are responsible for maintaining their competency to work under this PGD
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD an any associated organisational policy.	

2. Clinical condition or situation to which this PGD applies:	
Clinical condition or situation to which this PGD applies	Contraception
Inclusion criteria	• Individual (age from menarche to 50 years) presenting for contraception. • Informed consent given.
Exclusion criteria	• Clients not suitable for treatment at BPAS *(N.B. please refer to BPAS suitability criteria)* • 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 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 *(excluded from treatment at BPAS)* **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). **Gastro-intestinal conditions** • Severe decompensated cirrhosis. • Benign liver tumour (hepatocellular adenoma).
Cautions/Circumstances in which further advice should be sought (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 refer to the BPAS Safeguarding and Management of Clients Aged under 18 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 • Ensure individuals are informed on Long Acting Reversible Contraception (LARC), 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 an 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.
Arrangements for referral for medical advice	• Inform and discuss with the doctor in clinic. If not available, discuss with a regional clinical director • In the event of a medical emergency, e.g. anaphylaxis, provide immediate care in line with UK Resuscitation Council guidance, dial 999 to summon a paramedic response and initiate emergency transfer to NHS care • Document findings/action taken in client's record

3. Description of treatment:	
Name, strength and formulation medicine	Medroxyprogesterone Acetate 150 mg in 1 mL Injection (vial/pre-filled syringe)
Legal category	POM
Route / method 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.

Indicate any off-label use (if relevant)	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 administered after day 5 of a cycle • Can be administered 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 after last UPSI. • 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.

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.**
Quantity to be supplied	Single dose is to be administered per episode of care.
Storage	Stock must be securely stored in accordance with the BPAS Medicines Management policy and in conditions in line with the SmPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	The efficacy of IM DMPA is **not** reduced with concurrent use of enzyme-inducing drugs. All concurrent medications, including those purchased should be considered for interactions. A detailed list of drug interactions is available in the individual product SmPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and, as this PGD supports the administration of hormonal contraception, FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ 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 available in the SmPC, 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 • 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. If overdose or severe adverse reaction suspected manage following local policy. If necessary, seek appropriate emergency medical advice and assistance.
Additional facilities and supplies	• Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000)
Management and reporting procedure for adverse reactions	Document any adverse effects in the client's clinical records. If necessary, seek appropriate emergency medical advice and assistance as clinically indicated. Serious adverse drug reactions should be reported to the MHRA via https://yellowcard.mhra.gov.uk/ Adverse drug reactions must also be reported via Datix, including drug name, strength, formulation, batch numbers and expiry dates.
Written information and further advice to be given to the individual or carer	• 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.
Follow-up advice to be given to the individual or carer	• 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 to be kept	The following must be recorded in the client records in line with the NMC Code and BPAS' Record Keeping policy, using black ink if written:
	
	Record:
	• The consent of the individual and
	  • If individual is under 13 years of age record action taken
	  • 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 consent of the individual and if individual not competent to consent record action taken
	• Name of individual, 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
	• 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 product in line with local procedures • Advice given, including if excluded or declines treatment • Inclusion or exclusion from PGD • Individual has been advised on the date/s for next appointment as required • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the marketing authorisation • Name and signature (which may be an electronic signature) of the clinician supplying and administering the medicine • Recorded that administration is via 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. 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 clear, legible and contemporaneous.**

4. References and other source material:

- 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 Guidance: Progestogen-only Injectable Contraception (December 2014, amended July 2023) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-injectables-dec-2014/
- Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/
- 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/
- UK Resuscitation Council, 2021. Adult basic life support Guidelines | Resuscitation Council UK

5. Audit and ongoing monitoring of this PGD

Please refer to the 'Audit' section of the BPAS Patient Group Direction policy for additional guidance in relation to PGD audit.

The PGD audit tool is available here: British Pregnancy Advisory Service - Audit Tools - All Documents (sharepoint.com).

Units must retain a local copy of the completed audit tool as evidence.

The PGD audit criteria include:

1. Staff member has named, dated and signed the relevant PGD document

2. Client is documented as being referred to a medical practitioner if they are excluded from treatment under the PGD and there is no suitable alternative.
3. Date and time of supply / administration is on the prescription record / CAS2.
4. Client details – name, date of birth, allergies and any previous adverse effects are on the prescription record / CAS2.
5. Details of the medicine – name, strength, dose frequency, quantity, route and site (if by injection) of administration are on the prescription record / CAS2.
6. A statement that supply or administration is by using a PGD is on the prescription record / CAS2.
7. Name and signature (which may be electronic for CAS2 records) of the health professional supplying or administering the medicine is on the prescription record / CAS2.
8. Relevant information was provided to the client or their carer.
9. Client not documented to be allergic to the drug.
10. Paper documentation in related to PGDs are in black ink only.
11. Where appropriate for the medication, correct scheduling has been discussed.
12. Client does not meet any exclusions or contraindications listed in the most up to date PGD.

Appendix A: Approved Practitioner List

Patient Group Direction (PGD) name:	Administration of intramuscular (IM) medroxyprogesterone acetate (DMPA) injection (150mg/1ml)	
	Valid from: 01/11/2023	**Expiry: 31/07/2026**

Registered health professional

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove 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. The practitioner MUST sign this document before they can work under this PGD.

I confirm that I have read and understood the contents of this PGD. I confirm that I am willing and competent to work to this PGD within my professional code of conduct.				
Name (print)	**Designation**	**NMC PIN**	**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 for the above named health care professionals who have signed the PGD to work under it.				
Name	**Position**	**BPAS Treatment Unit**	**Signature**	**Date:**

Note to authorising manager

- Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
- If registered health professional signatures need to be added at a later date, e.g. due to staffing changes, a separate Approved Practitioner List must be signed, ensuring the correct PGD name and version is detailed.
- This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD for the period specified in the BPAS PGD policy.
- This list must be stored by the Treatment Unit in a designated folder and be available for immediate inspection, alongside any training / competency records. If a registered professional works across multiple sites, they must sign the Approved Practitioner List for each PGD at each BPAS site where they will use the PGD.