Brighton and Sussex University Hospitals NHS 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)

Supply and/or administration of subcutaneous medroxyprogesterone acetate (SC-DMPA) injection in Brighton and Sussex University Hospitals NHS Trust Sexual Health & Contraception (SHAC) Service

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1.0 May 2020	New template

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.

Approved date JUNE 2020 Expiry date 31 MAY 2023

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	May 2020
Review date	November 2020
Expiry date:	May 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 April 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
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

PGD approval - meets local need and guidelines

Name	Job title and organisation	Signature	Date
Lead author: Reproductive Health PGDs Short Life Working Group	As listed on Page 2/3		
Lead Doctor: Dr Juliet Bowie	Associate Specialist, SHAC Service, BSUH	Email approval	02/07/20
Lead pharmacist: Claire Richardson	Lead Pharmacist, HIV & Sexual Health Service, BSUH	Email approval	07/07/20
Lead Clinician for area: Dr Debbie Williams	Consultant (HIV & GUM), SHAC, BSUH	Email approval	02/06/20
Reviewed by: Dr Daniel Richardson	Consultant HIV & SHAC Service, BSUH	Email approval	01/07/20
Representative of other professional group using PGD: Wendy Gardiner	Advanced Nurse Practitioner, SHAC Service, BSUH	Email approval	01/07/20

Organisational authorisations

Brighton & Sussex University Hospitals NHS Trust authorises this PGD for use by the services or providers listed below:
Sexual Health & Contraception (SHAC) Service.
Limitations to authorisation
Only Registered Nurses who work within the SHAC Service, hold a relevant contraception qualification, and are signed to the PGD.

Name	Signature & Name	Date
Chair of PGD Group	Joanne Pendlebury	Email approval 07/07/20
Chief Pharmacist	Mike Cross	Email approval 24/07/20
Medicines Governance Group chair	Mike Okorie	Email approval 27/07/20

Local enquiries regarding the use of this PGD may be directed to Bsuh.pgdgroup@nhs.net or PGD group chair.

Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

Approved date JUNE 2020 Expiry date 31 MAY 2023

1. Characteristics of staff

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 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. Register and complete PGD training module (certificate can be printed out as evidence) https://portal.e-lfh.org.uk/ (3 yearly) Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions. Has undertaken appropriate Trust resuscitation training.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for contraception supply. • 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, including: ○ PGD e-learning 3 yearly ○ Up to date with mandatory training
The decision to supply 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 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, present before commencing the method **Cardiovascular Disease** • Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic first attack. • Individuals with multiple risk factors for cardio-vascular disease (such as smoking, diabetes, hypertension, obesity and dyslipidaemias) **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 SC-DMPA first line for contraception because of its effect on bone mineral density. SC-DMPA may be considered if all alternative contraceptive options are unsuitable or unacceptable. • 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 IUD/LARC. If an IUD/LARC is unacceptable/unsuitable and SC-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 (e.g. Sayana Press®) 104 mg in 0.65mL injection (pre-filled syringe) **Note:** • This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to. • See http://www.mhra.gov.uk/spc-pil/ or http://www.medicines.org.uk for further information and further brand information including full details of adverse effects and interactions.
Legal category	POM
Route of administration	Subcutaneous injection. **Advice for administration:** • Shake the syringe vigorously before administration. • Ensure that the full injection is given. The medication should be injected slowly over approximately 5-7 seconds with the needle pointing downwards. • Inject into the upper anterior thigh or the anterior abdomen, avoiding bony areas or the umbilicus and areas of inflamed or broken skin. • Do not massage the site after the administration of the injection. **NOTE – if administering SC-DMPA the healthcare professional must only use a pre filled syringe from stock under this PGD and must not use any pre filled syringe which has been supplied by the individual.**
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 many of the available products but which are included within FSRH guidance: • Supply and administration at 10 weeks after last injection. However administration at under 13 weeks from the last administration should not be routinely or consistently

	undertaken and 13 week intervals should be advised. • Supply and administration up to 14 weeks after last injection. • Supply and administration after five days postpartum if not breast feeding/before six weeks postpartum if breast feeding. FSRH guidance supports the use of SC-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 pre-filled injection (104mg/0.5ml) on day 1-5 of the menstrual cycle with no need for additional protection. • SC-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 SC-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. • SC-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, SC-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, and unprotected sexual intercourse (UPSI) has occurred the injection should be given and refer to FSRH current guidelines for advice on the need for additional

	contraception. • 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 SC-DMPA and has no contraindications to its use. **Note** - in women of all ages, 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. In particular, in women with significant lifestyle and/or medical risk factors for osteoporosis, other methods of contraception should be considered prior to use of SC-DMPA.
Quantity to be supplied	• If being administered under this PGD a single dose (one pre-filled syringe) is to be administered per episode of care. • If for self-administration supply up to twelve months supply (up to 4 pre-filled 0.65 ml pre-filled syringes).
Storage	Medicines must be stored securely according to national guidelines.
Drug interactions	The efficacy of SC-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 SC-DMPA (but may not reflect all reported adverse effects): • Headache • Injection site reactions including possible irreversible skin dimpling or indentation at injection site • 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 between current use of DMPA and breast cancer – any increased risk is likely to be small and reduce with time after stopping. • Weak association between cervical cancer (Human Papilloma Virus (HPV)) and use of SC-DMPA.
Management of and reporting procedure for adverse	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the

reactions	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 • Demonstrate to individual how to self-administer according to manufacturer's instructions/signpost to video tutorial. • Advise individual on safe disposal of sharps according to local policy. • Advise individual about need to return for repeat injection if she experiences any difficulty with administration. • 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 she has any concerns • Return for review annually.
Records	**Record:** • 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 supply and whether administered • Dose supplied/administered • Quantity supplied • Batch number and expiry date of administered and/or supplied doses • Advice given, including advice given if excluded or declines treatment • That the individual has been assessed as competent to self-administer and trained to self-administer • That the individual has been supplied with the required equipment, including sharps bin for disposal • Individual has been advised on the dates/s for repeat self-injection and/or 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 supply outside the terms of the product marketing

	authorisation • Recorded that supply/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.

Audit

Plan for audit, It is essential for PGD renewal that audits have occurred**.**	Service audit to be completed using the recommended BSUH PGD audit template. N. B. Individual PGD users should keep records to audit their own use of PGDs / procedures.
Frequency	Minimum of once in lifetime of PGD 2 years after start date of PGD to inform PGD review.
Nominated lead to manage audit	Advanced Nurse Practitioner, SHAC Service will manage Service PGD audit process and support / guide those completing the audit. SHAC Nurse(s) who use the PGD will complete the service audit.

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/ • FSRH CEU Statement: Self-Administration of Sayana Press® (September 2015) https://www.fsrh.org/standards-and-guidance/documents/ceustatementsayanaselfadmin/ • 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/

	• Learning for Health https://portal.e-lfh.org.uk/ • BSUH policies and procedures: ➢ C085 – Policy for Patient Group Directions: accessed on BSUH intranet https://nww.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions ➢ SHAC Service Standard Operating Procedure for supply of medicines following telephone / video consultations

Appendix A - Registered health professional authorisation sheet

PGD Name/Version: ***Supply and/or administration of subcutaneous medroxyprogesterone acetate (SC-DMPA) injection / Version 1***

Valid from: June 2020 **Expiry: 31 March 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 Brighton and Sussex University Hospitals NHS 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.

Approved date JUNE 2020 Expiry date 31 MAY 2023

SHAC SERVICE RETENTION OF PGD AUTHORISATION RECORDS

Records of the authorisation of nurses for the use of this PGD are stored as follows:

- **HARD COPY:**

  A paper copy of the signature sheet will be kept with the PGD in the PGD Master Copy File in the SHAC Nurse Management Office.

- **ELECTRONIC RECORD:**

  - A scanned copy of each authorisation sheet to be saved.
  - An electronic record of SHAC Nurse authorisation for this PGD will be stored on the SHAC Service PGD Assessment Record database.
  - The scanned authorisation sheets and the database are stored in the shared Integrated Sexual Health file (within the specific PGD file).

- **INDIVIDUALS:**

  Individual nurses are provided with the PGD assessment sheet which details the assessment process for PGD approval for their own records. A copy of this document is stored in the individual nurses' Personal File.